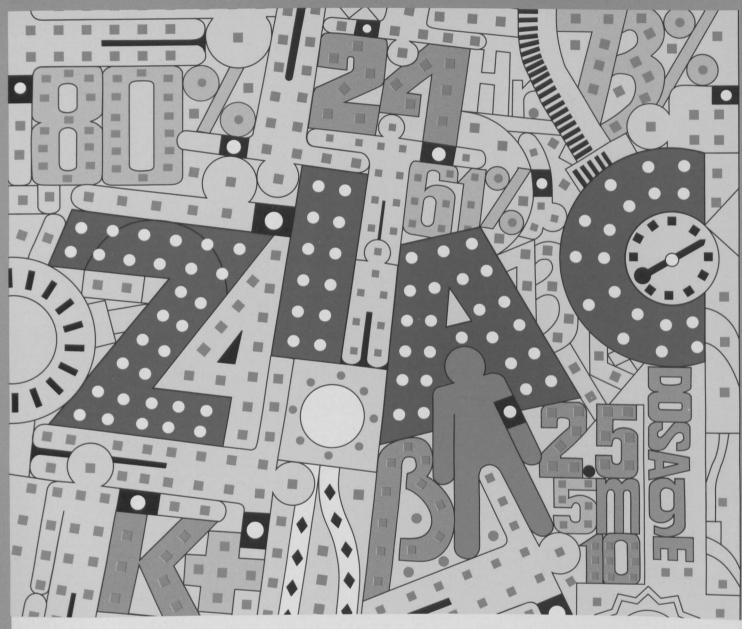
For first-line therapy in mild-to-moderate hypertension

Discover the classic benefits of a beta-blocker and a diuretic...now at low doses for a side-effect profile comparable to placebo1*



ZIAC controls mild-to-moderate hypertension in up to 80% of patients^{1†}

ZIAC controls blood pressure for a full 24 hours for true once-a-day dosing²

ZIAC minimizes traditional beta-blocker- and HCTZ-associated metabolic effects (hypokalemia, hyperuricemia, hypercholesterolemia, hyperglycemia)¹

*The two most common side effects — dizziness and fatigue — occurred at rates comparable to placebo.

[†]Clinical trial response rates were: 2.5 mg—61%; 5 mg—73%; 10 mg—80%.

ZIAC is contraindicated in patients in cardiogenic shock, overt cardiac failure (see WARNINGS section of full Prescribing Information), second- or third-degree AV block, marked sinus bradycardia, anuria, and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

Please see Brief Summary of Prescribing Information on adjacent page.

First-line therapy option

(bisoprolol fumarate-hydrochlorothiazide) 2.5, 5, & 10 mg Tablets with 6.25 mg HCTZ



(bisoprolol fumarate-hydrochlorothiazide) 2.5, 5, & 10 mg Tablets with 6.25 mg HCTZ

References:

Reterences:
 1. DeQuattro V, Weir MR. Bisoprolol fumarate/hydrochlorothiazide 6.25 mg: a new, low-dose option for first-line antihypertensive therapy. Adv Ther. 1993;10:197-206.
 2. Lewin AJ, Lueg MC, Targum S, et al. A dinical trial evaluating the 24-hour effects of bisoprolol/hydrochlorothiazide 5 mg/6.25 mg combination in patients with mild to moderate hypertension. Clin Cardiol. 1993;16:732-736.

Brief Summary

ZIAC™ (Bisoprotol Fumarate and Hydrochlorothiazide) Tablets

FOR FULL PRESCRIBING INFORMATION, PLEASE CONSULT PACKAGE INSERT.

ZIAC (bisoprolol fumarate and hydrochlorothiazide) is indicated for the treatment of hypertension. It combines two antihypertensive agents in a once-daily dosage: a synthetic beta,-selective (cardioselective) adrenoceptor blocking agent (bisoprolol fumarate) and a benzothiadiazine diuretic (hydrochlorothiazide).

CLINICAL PHARMACOLOGY

At doses ≥ 20 mg bisoproiol furnarate inhibits beta, adrenoreceptors located in bronchial and vascular musculature. To retain relative selectivity, it is important to use the lowest effective dose.

CONTRAINDICATIONS

Cardiogenic shock, overt cardiac failure (see WARNINGS), second or third degree AV block, marked sinus bradycardia, anuria, and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

WARNINGS

Cardiac Failure: Beta-blocking agents should be avoided in patients with overt congestive failure.

Patients Without a History of Cardiac Failure: Continued depression of the myocardium with beta-blockers can precipitate cardiac failure. At the first signs or symptoms of heart failure, discontinuation of ZIAC should be

Abrupt Cessation of Therapy: Abrupt cessation of beta-blockers should be avoided. Even in patients without overt coronary artery disease, it may be advisable to taper therapy with ZIAC over approximately 1 week with the patient under careful observation. If withdrawal symptoms occur, beta-blocking agent therapy should be reinstituted, at

Peripheral Vascular Disease: Beta-blockers should be used with caution in patients with peripheral vascular

OSPASTIC DISCASE: PATIENTS WITH BRONCHOSPASTIC PULMONARY DISEASE SHOULD, IN GENERAL

NOT RECEIVE BETA-BLOCKERS.

Anesthesia and Mejor Surgery: It used perioperatively, particular care should be taken when anesthetic agents that depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used.

Diabetes and Hypoglycemia: Beta-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be cautioned. Also, latent diabetes mellitus may become manifest and diabetic patients given thazides may require adjustment of their insulin dose.

Thyprotoxicesiz: Beta-adrenergic blockade may mask clinical signs of hyperthyroidism. Abrupt withdrawal of beta-blockade may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate thyroid storm.

Remai Disease: Cumulative effects of the thiazides may develop in patients with impaired renal function. In such patients, thiazides may precipitate azotemia. In subjects with creatinine clearance less than 40 mL/min, the plasma haf-file of bisoprolol furmarate is increased up to threefold, as compared to healthy subjects. Hepetic Disease: ZIAC should be used with caution in patients with impaired hepatic function or progressive liver

PRECAUTIONS

General: Electrolyte and Fluid Balance Status: Periodic determination of serum electrolytes should be performed, and patients should be observed for signs of fluid or electrolyte disturbances. Thiazides have been shown to increase the urinary exception of magnesium; this may result in hypomagnessemia. Hypokalemia may develop. Hypokalemia and hypomagnessemia can provoke ventricular arrhythmias or sensitize or exaggerate the response of the heart to the toxic effects of digitalis. Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction rather than salt administration, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice. Parathyroid Disease: Calcium excretion is decreased by thiazides, and pathologic changeain the parathyroid glands, with hypercalcemia and hypophosphatemia, have been observed in a few patients on prolonged thiazide chierapy. Hyperuricemia: Hyperuricemia: Hyperuricemia are actually of the discontinual districtions and the parathyroid diversions and may be precipitated in certain patients receiving thiazide diuretics. Bisoproiol fumarate, alone or in combination with HCT2, has been associated with increases in uric activities. Bisoproiol fumarate, alone or in combination with HCT2, has been associated with increases in uric activities. Bisoproiol fumarate, alone or in combination with HCT2, has been associated with increases in uric activity of the parathyroid General: Electrolyte and Fluid Balance Status: Periodic determination of serum electrolytes should be performed,

ZIAC should be used with caution when myocardial depressants or inhibitors of AV conduction or anti-

Clonidine.

ZIAC should be used with caution when myocardial depressants or inhibitors of AV conduction or antiarrhythmic agents are used concurrently.

Bisoprolof Fumarate: Concurrent use of rifampin increases the metabolic clearance of bisoprolol fumarate, shortening its elimination half-life. Pharmacokinetic studies document no clinically relevant interactions with other agents given concomitantly, including thiazide diuretics, digoxin and cimetidine. There was no effect of bisoprolol fumarate on prothorombin times in patients on stable doses of warfarin.

While taking beta-blockers, patients with a history of severe anaphylactic reaction may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic and may be unresponsive to the usual doses of epineprine used to treat allergic reactions.

Hydrochlorothiazide: The following drugs may interact with thiazide diuretics. Alcohol, barbiturates, or narcof-epineprine used to treat allergic reactions.

Hydrochlorothiazide: The following drugs may interact with thiazide diuretics. Alcohol, barbiturates, or narcof-epineprine used to treat attallergic reactions.

Hydrochlorothiazide: The following drugs may interact with thiazide diuretics. Alcohol, barbiturates, or narcof-septentiation of orthostable chyolension may occur. Dosage adjustment of the antidiabetic drugs (oral agents and insulin) may be required. Other antihypertensive drugs—additive effect or potentiation. Cholestyramine and colestipol resins bind the hydrochlorothiazide and reduce it absorption in the gastrointestinal tract by up to 85 and 43 percent, respectively. Corticosteroids, ACTH –intensificed to preclude their use. Possible increased responsiveness to muscle relaxants, nondepolarizing. Generally, lithium should not be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. The administration of a nonsteroidal anti-inflammatory agent can reduce the diuretic.

In patients receiving thiazides, sensitivity reacti

post-sympathectomy patient.

Laboratory Test Interactions: Based on reports involving thiazides, ZIAC may decrease serum levels of protein-bound indine without signs of thyroid disturbance. Because it includes a thiazide, ZIAC should be discontinued before carrying out tests for parathyroid function (see PRECAUTIONS—Parathyroid Disease).

ZIAC: Bisoproloi fumarate/H6.25 mg is well tolerated in most patients. Most adverse effects (AEs) have been mild and transient. In more than 65,000 patients treated worldwide with bisoproloi fumarate, occurrences of bronchospasm have been rare. Discontinuation rates for AEs were similar for B/H6.25 mg and placebo-treated patients. In the United States, 252 patients received bisoproloi fumarate (2.5, 5, 10, or 40 mg)/H6.25 mg was administered for 4 weeks. In Study 2, bisoproloi fumarate 5/H6.25 mg was administered for 4 weeks. In Study 3, bisoproloi fumarate 5/H6.25 mg was administered for 12 weeks. All adverse experiences, whether drug-related or not, and drug-related adverse experiences in patient streated with B2.5-10/H6.25 mg, reported during comparable, 4 week treatment periods by at least 2% of bisoproloi fumarate/H6.25 mg-treated patients (plus additional selected adverse experiences) are presented in the following table:

ZIAC™ (Bisoproiol Fumerate and Hydrochlorothiazide) Tablets

% of Patients with Adverse Experiences*

Body System/ Adverse Experience	All Adve	rse Experiences	Drug-related Adverse Experiences	
	Placebo*	B2.5-40/H6.25 [†]	Placebo [†]	B2.5-10/H6.25 [†]
	(n = 144) %	(n = 252)	(n = 144) %	(n = 221)
Cardiovascular	70	/0	/0	70
bradycardia	0.7	1.1	0.7	0.9
arrhýthmia	1.4	0.4	0.0	0.0
peripheral ischemia	0.9 0.7	0.7	0.9	0.4
chest pain	0.7	1.8	0.7	0.9
Respiratory			***	
bronchospasm	0.0	0.0 2.2 0.7 2.1	0.0	0.0
cough	1.0	2.2	0.7	1.5
rhinitis	2.0	0.7	0.7	0.9
URI	2.3	2.1	0.0	0.0
Body as a Whole			0.0	0,0
asthenia	0.0 2.7	0.0	0.0	0.0
fatique	2.7	4.6	1.7	3.0
peripheral edema	0.7	1.1	0.7	0.9
Central Nervous System			•	
dizziness	1.8	5.1	1.8	3.2
headache	4.7	4.5	2.7	0.4
Muscujoskejetaj				•
muscle cramps	0.7	1.2	0.7	1,1
myalgia	1.4	2.4	0.0	0.0
Psychiatric				•.•
insomnia	2.4	1.1	2.0	1.2
somnolence	0.7	1.1	0.7	0.5
loss of libido	0.7 1.2 0.7	0.4	1.2	0.4
impotence	0.7	0.4 1.1	0.7	1.1
Gastrointestinal			•	•••
diarrhea	1.4	4.3	1.2	1,1
nausea	0.9 0.7	1.1	0.9	Ò.Ì
dyspepsia	0.7	1.2	0.9 0.7	0.9

Averages adjusted to combine across studies.

Combined across studies.

Other adverse experiences that have been reported with the individual components are listed below.

Bleaprolof Fumarate: In clinical trials worldwide, a variety of other AEs, in addition to those listed above, have been reported. While in many cases it is not known whether a causal relationship exists between bisoproloi and these AEs, they are listed to alert the physician to a possible relationship. Central Mervous System: Unsteadiness, vertigo, syncope, paresthesia, hyperesthesia, sleep disturbance/vivid dreams, depression, anxiety/restlessness, ecreased concentration/memory. Cardiovascular: Papitations and other rhythm disturbances, cold extremities, claudication, hypotension, orthostatic hypotension, chest pain, congestive heart failure. Gastroinestinal: Gastric/epigastric/abdominal pain, peptic ulcer, gastritis, vomiting, constipation, dry mouth. Musculoskeletal: Arthralgia, muscle/joint pain, back/neck pain, twitching/tremor. Skin: Rash, acne, eczema, sporiask in irritation, pruritus, purpura, flushing, sweating, alopecia, dermatitis, exclusitive dermatitis (very rarely). Special Senses: Visual disturbances, coular pain/oressure, abnormal lacrimation, tinnitus, decreased hearing, earche, taste abnormalities. Metabolic: Gout. Respiratory: Asthma, bronchitis, dyspnea, pharyngitis, sinustiis. Genito-urinary: Peyronle's disease (very rarely), cystitis, renal colic, polyuria. General: Malaise, edema, weight gain, angloedema.

urniary: Peyronie s disease (very ratery); cyscurs, renar conc. polydria. General: Metalase, gerena, Weight gaint angloedema.

In addition, a variety of adverse effects have been reported with other beta-adrenergic blocking agents and should be considered potential adverse effects: Central Nervous System: Reversible mental depression progressing to catatonia, hallucinations, an acute reversible syndrome characterized by disorientation to time and place, emotional liability, slightly clouded sensorium. Allergic: Fever, combined with aching and sore throat, laryngo-spasm, and respiratory distress. Hematologic: Agranulocytosis, thrombocytopenia. Gestraintestinal Mesenteric arterial thrombosis and ischemic collitis. Miscellaneous: The oculomucocutaneous syndrome associated with the beta-blocker practiol has not been reported with bisoprolol furnarate during investigational use or extensive foreign marketing experience.

Hydrochlorothiazide: The following adverse experiences, in addition to those listed in the above table, have been reported with hydrochlorothiazide (generally with doses of 25 mg or greater). General: Weakness. Central Nervous System: Vertigo, parestinesia, restlessness. Cardiovascular: Orthostatic hypotension (may be potentiated by alcohol. barbiturates, or nacrobics). Gestroinlestinal: Anorexia, gastric irritation, cramping, constitucino, jaundice (intrahepatic cholestatic jaundice), pancreatitis, cholecystifis, sialadentis, dry mouth. Musculoskelati: Muscle spasm. Hypersensitive Reactions: Purpura, photosensitivity, rash, urticaria, necrotizing anglitis (vasculistis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary admandition, anaphylactic reactions. Special Senses: Transient blurred vision, xanthopsia. Metabolic: Gout. Gentourinary: Sexual dysfunction, renal failure, renal dysfunction, interstitial nephritis.

LABORATORY ABNORMALITIES

ZIAC: Because of the low dose of hydrochlorothiazide in ZIAC, adverse metabolic effects with B/H6.25 mg are less frequent and of smaller magnitude than with HCTZ 25 mg.

Treatment with both beta-bickers and thiazide diuretics is associated with increases in uric acid. Mean increases in serum trigly-cerides were observed in patients treated with bisoproloi fumarate and hydrochlorothiazide 6.25 mg. Total cholesterol was generally unaffected, but small decreases in HDL cholesterol

Other laboratory abnormalities that have been reported with the individual components are listed below.

Bisoprolol Fumarate: In clinical trials, the most frequently reported laboratory change was an increase in serum triglycerides, but this was not a consistent finding.

Sporadic liver test abnormalities have been reported. In the U.S. controlled trials experience with bisoprolol fumarate treatment for 4 to 12 weeks, the incidence of concomitant elevations in SGOT and SGPT of between 1 to 2 times normal was 3.9%, compared to 2.5% for placebo. No patient had concomitant elevations greater than twice

normal.

In the long-term, uncontrolled experience with bisoproloi fumarate treatment for 6-18 months, the incidence of one or more concomitant elevations in SGOT and SGPT of between 1-2 times normal was 6.2%. The incidence of multiple occurrences was 1.9%. For concomitant elevations in SGOT and SGPT of preater than twice normal, the incidence was 1.5%. The incidence of multiple occurrences was 0.3%. In many cases these elevations were attributed to underlying disporders, or resolved during continued treatment with bisoproiol fumarate. Other laboratory changes included small increases in uric acid, creatinine, BUN, serum potassium, glucos, and phosphorus and decreases in WBC and platelets. There have been occasional reports of eosinophilia. These were generally not of clinical importance and rarely resulted in discontinuation of bisoproiol fumarate. As with other beta-blockers, ANA conversions have also been reported on bisoproiol fumarate. About 15% of patients in long-term studies converted to a positive titer, although about one-third of these patients subsequently reconverted to a negative titer while on continued therapy.

Hydrochlorethiazide: Hyperglycemia, plycosuria, hyperuricemia, hypokalemia and other electrolyte imbalances (see PRECAUTIONS), hyperlipidemia, hyporaclaemia, agranulocytosis, thrombocytopenia, aplastic anemia, and hemolytic anemia have been associated with HCT2 therapy.

See DOSAGE AND ADMINISTRATION section in package insert for complete dosing and precautionary information.

information



ADVANTUS PHARMACEUTICALS and LEDERLE LABORATORIES DIVISION American Cyanamid Company Pearl River, NY 10965

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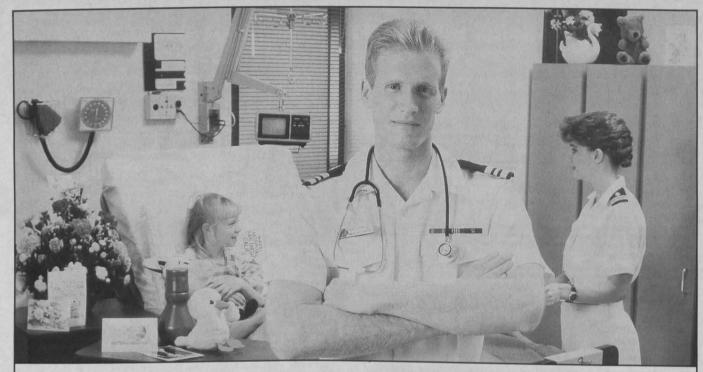






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[†] Combined across studies.



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Paul R. Young, M.D. **Executive Editor**

Esgic*plus* **"tablets**

Butalbital 50mg (Warning: May be habit forming) /Acetaminophen 500mg/Caffeine 40mg

References: 1. Benson GD. Hepatotoxicity following the therapeutic use of antipyretic analgesics. Am J Med. 1983;75(suppl 5A):85-93. 2. Juck H. Effects of aspirin and acetaminophen in gastro-intestinal hemorrhage. Arch Intern Med. 1981;141:316-321. 3. Mielke CH Jr. Comparative effects of aspirin and acetaminophen on hemostasis. Arch Intern Med. 1981;141:305-310. 4. Hansten PD. Drug Interactions. 5th ed. Philadelphia. PA: Lea & Febiger; 1985, p. 95. 5. Insel PA. Analgesic-antipyretics and antiinflammatory agents; drugs employed in the treatment of rheumatold arthritis and gout. In: Gilman AG. Rall TW, Niss AS, Taylor P, eds. The Pharmacological Basis of Therapeutics. 8th ed. New York, NY: Pergamon Press; 1990:638-681.

ESGIC-PLUS™ Tablets

(Butalbital, Acetaminophen and Caffeine Tablets, USP)

Brief Prescribing Information: (Please see package insent for full prescribing information) Each Esgic-plus**
Tablet contains: Butaibitat, USP 50 mg. WARNING: May be habit forming. Acetaminophen, USP 500 mg.
Caffeine, USP 40 mg. In addition each tablet contains the following inactive ingredients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide and stearic acid.

Cartenie, USP 40m. In addition each tablet contains the following inactive ingredients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide and stearic acid.

CONTRAINDICATIONS: This product is contraindicated under the following conditions: * Hypersensitivity or intolerance to any component of this product: * Patients with porphyria. WaRNINGS: Butabital is habit-forming and potentially abusable. Consequently, the extended use of this product is not recommended.

PRECAUTIONS: General: Esgic-plus** Tablets should be prescribed with caution in certain special-risk patients, such as the identry or debitated, and those with severe impairment of renal or hepatic function, or acute abdominal conditions. Information for Patients: This product may impair mental and/or physical abilities required for the performance of potentially hazardous tasks such as the didn't or debitation of the performance of potentially hazardous tasks such as driving a car or operating machinery. Such tasks should be avoided while taking this product. Alcohol and other NS depressants may produce an additive CNS depression, when taken with this combination product, and should be avoided. Butabital may be habit-forming. Patients should take the drug only for as long as it is prescribed, in the amounts prescribed, and nome frequently than prescribed. Laboratory Tests: In patients with severe hepatic or renal disease, effects of therapy should be monitored with serial liver and/or renal function tests. Drug Interactions: The CNS effects of butabital may be enhanced by monoamine oxidase (MAO) inhibitors. Esgic-plus** Tablets may enhance the effects of other narcotic analgesics, alcohol, general anesthetics, tranquilizers such as chiordiazepoxide, sedative-hyprodics, or other CNS depressants, causing increased CNS depression. Drug/Laboratory Test Interactions: Acetaminophen may produce false-positive test results for urinary 5-hydroxyindoleacetic acid. Carcinogenesis, magarener of Fertility. No adequate studies have been con

importance of the drug to the mother. Pediatric Use: Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS: Frequently Observed: The most frequently reported adverse reactions are drowsiness, light-headedness, dizziness. sedation. Shortness of breath, nausea, vomiting, abdominal pain, and intoxicated releding, Infrequent, Contral Nervous: headache, shaky feeling, tingling, agitation, fainting, fatigue, heavy eyelids, high energy, hot spells, numbness, sluggishness, seizure. Mental confusion, excitement or depression can also occur due to intolerance particularly in eiderly or debilitated patients, or due to overdosage of butalbital. Autonomic Nervous: dry mouth, hyperhidrosis. Gastrointestinal: difficulty swallowing, heartburn, flatuence, constipation. Cardiovascular, tachycardia. Musculosketal: lep pain, muscle tatique. Genitourinary: diuresis. Miscellaneous: prurtius, fever, carache, nasal congestion, tinnitus, euphoria, allergic reactions. Several cases of dermatological reactions, including toxic epidermal necrolysis and erythema multitorime, have been reported. The following adverse drug eviders dry borne in mind as potential effects of the components of this product. Potential effects of high dosage are listed in the OVEROOSAGE section. Acetaminophen: allergic reactions, rash, thrombocytopenia, agranulocytosis. Carfenec. cardiac stimulation, irritability, tremor, dependence, nephrotoxicity, hyperglycemia.

DNUG ABUSE AND DEPENDENCE: Abuse and Dependence: Butalbital: Barbiturates may be habit-forming: Tolerance, psychological dependence, and physical dependence may occur especially following prolonged use of high doses of barbiturates. The average daily dose for the barbiturate addict is usually about 1500 mg. As tolerance to parbiturates develops, the amount needed to maintain the same level of intoxication increases tolerance to a fatal dosage becomes smaller. The lethal dose of a barbiturate is tar less if alcohol is so ingested. Major withorawal symptoms

drawal regimens. One method involves initiating treatment at the patient's regular dosage level and gradually decreasing the daily dosage as collected by the patient.

WERDUSABE: Following an acute overdosage of Esgic-plus'" Tablets, toxicity may result from the barbiturate or the acetaminophen. Toxicity due to caffeine is less likely, due to the relatively small amounts in this formulation.

Signs and Symptoms: Toxicity due to caffeine is less likely, due to the relatively small amounts in this formulation.

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Signs and Symptoms: Toxicity due to caffeine is less likely and patients and supposition and another patients.

Signs and signs of stabilities and adults, hepatic toxicity has rarely been raported with acute overdose of less than 10 grams, or stabilities with less han 15 grams. Acute caffeine poisoning may cause insomnia, rest-lessness, tremor, and delirium, tachycardia and extrasystoles.

Treatment: A single or multiple overdose with this combination product is a potentially lental polydrug overdose, and consultation with a regional posurous control center is recommended. Immediate treatment includes support of cardiorespiratory function and measures to reduce drug absorption.

Toxicity pharyngeal and laryngeal reflexes). Oral activated charcoal (1 g/kg) should foliow gastro centrol regions and s

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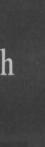
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Generally well tolerated at usual doses.[†]



Plendil

(felodipine) Tablets, 5 mg, 10 mg

Because you consider the whole patient.

*1993 IMS NDTI Prescription Data.

*Peripheral edema, generally mild, was the most common adverse event in clinical trials.

PLENDIL is contraindicated in patients who are hypersensitive to this product. Please see brief summary of Prescribing Information on page following next page.



BRIEF SUMMARY

PLENDIL

GELLODIEINE

EXTENDED RELEASE TABLETS

INDICATIONS AND USAGE

PLENDIL 1 is indicated for the treatment of hypertension PLENDIL may. be used alone or concountantly with other antihypertensive agents

CONTRAINDICATIONS

PEENDII is contraindicated in patients who are hypersensitive to this product.

PRECAUTIONS

Hypotension: Felodipme: Tike other calcium antagonists, may occasimally precipitate significant hypotension and farely syncope. It may lead to reflex tachycardia which in susceptible individuals may precipitate angina pectoris. (See ADVERSE REACHONS.)

Heart Failure: Although acute hemodynamic studies in a small miniber of patients with NYHA Class II or III theart failure treated with telodipine have not demonstrated negative motopic effects, safety in patients with heart failure has not been established. Cauthou their fore should be exercised when using PTENDIL in patients with heart lathre or compromised ventricular function, particularly in combina-tion with a fieta blocker.

Elderly Patients or Patients with Impaired Liver Function: Patients over 65 years of age or patients with impaired liver function may have over to years in age or patients with industrial most not relevated plasma concentrations of felodiquie and may therefore respond to lower doses of PTENDII. These patients should have their blood pressure monitored closely during dosage adjustment of PTENDII and Should randerly regime doses above 10 mg. (See GLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION sections of com-

Peripheral Edema: Peripheral edema, generally mild and not asso caled with generalized fund retention, was the most common adverse event in the chinical trials. The incidence of peripheral edema was both dose, and age dependent. Trequency of peripheral edema ranged from about 10 per daily to about 30 percent in those over 60 years of age taking 20 ing daily. This adverse effect generally occurs within 2-3 weeks of the im-

Information for Patients

Patients should be instructed to take PTENDU whole and not to cush or chew the tablets. They should be fold that unid grigival disperplasia (guin swelling) has been reported. Good dental hygiene creases its incidence and severily

NOTE: As with many other drings, certain advice to patients being treated with PLENDIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects

Drug Interactions

urig interactions
Beta-Blocking Agents: A pharmacokinetic study of felodipme in
commeton with inetopiolal demonstrated in significant effects on
the pharmacokinetic of felodipme. The ADC and Conce of metopiolal
however were increased approximately 31 and 38 percent, respectively. In controlled clinical trials however, beta blockers including metoprofol were concurrently administered with felodipine and were well tolerated.

Cimetidine: In healthy subjects pharmacokinetic studies showed an approximately 50 percent increase in the area under the plasma concentration time curve (AUC) as well as the C_{max} of feladipine when given concomitantly with concluding. It is anticipated that a clinical ly significant interaction may occur in some hypertensive patients. Decelors, it is recommended that low doses of PFENDIE be used when given concountantly with concluding

Digoxin: When given concountantly with felodipine the peak plasma concentration of digoxin was significantly increased. There was how ever, no significant change in the AUC of digoxin

Anticonvulsants: In a pharmar oknoele, study maximum plasma encentrations of lefodipine were considerably lower in epideptic patients un long term anticonvulsant therapy (e.g., plieaytoin carba mazepine of phenobarbital) than in healthy volunteers. In such patients, the mean area under the felodigine plasma concentration, time curve was also reduced to approximately six percent of that observed in healthy volunteers. Since a clinically significant interac-tion may be anticipated, alternative antihypertensive therapy should be considered in these patients.

Other Concomitant Therapy: In healthy subjects there were no chin ically significant interactions when telodipine was given concomitantly with indomethacm or spironolactorie

Interaction with Food: See CEINICAL PHARMACOLOGY, Pharmaca knieda's and Metaholisarsection of complete Prescribing Information Carcinogenesis, Mutagenesis, Impairment of Fertility

In a two year carcinogementy study in rats led lelodipine at doses of $I=23.1\,$ or $69.3\,$ mg/kg/day (up to 28 times—the maximum recommended human dose on a my/m basis), a dose related increase in the incidence of beingh interstitial cell tumors of the testes (legdig cell tumors) was observed in treated male rats. These tumors were not observed in a similar study in mice at doses up to 1.38.6 ing/kg/day (28 times: the maximum recommended human dose on a ing/m ba.is). Telodipine, at the doses employed in the two year cat study. has been shown to lower testicular testosterone and to produce a cor-responding increase in serian Internizing hormione in rats. The Feydig Litumoi development is pussibly secondary to these hormona effects which have not been observed in man-

local aquamous cell hyperplasia compared to control was observed in the exophageal groove of male and female rats in all dose groups. No other drug related exophageal or gastire pathology was observed in the rats or with chronic administration or nuce and dogs. The latter species, like man, has no anatomical structure comparable to the esophageal groove

Telodipine was not carcinogenic when fed to mice at doses of up to 138,6 mg/kg/day (28 times: the maximum recommended human dose on a mg/m basis) for periods of up to 80 weeks in males and 99

Felodopine did not display any mutagenic activity *in vitro* in the Ames microbial mutagenicity test or in the mouse lymphoma forward mutation assay. No claslogenic potential was seen in vivo in the mouse micronucleus test at oral doses up to 2500 mg/kg (506 times the maximum recommended human dose on a mg/m-basis) or *in vitro* in a human lymphocyte chromosome aberration assay.

. A fertility study in which male and female rats were administered doses of $3.8,\,9.6$ or 26.9 mg/kg/day showed no significant effect of telodipine on reproductive performance.

Pregnancy

Pregnancy Category C

alies consisting of reduction in size and degree of ossification of the terminal phalanges in the fetuses. The frequency and severity of the changes appeared dose related and were noted even at the lowest dose. These changes have been shown to occur with other members of the dihydropyridme class and are possibly a result of compromised otenne blood flow. Similar fetal anomalies were not observed in rats given felodioine

In a teratology study in cynomolgus monkeys no reduction in the size of the terminal phalanges was observed but an abnormal position of the distal phalanges was noted in about 40 percent of the fetuses

Nonteratogenic Effects: A prolongation of partirition with difficult labor and an increased frequency of fetal and early postnatal deaths were observed in rats administered doses of 9.6 mg/kg/day (4 times the maximum human dose on a ing/m-basis) and above

Significant enlargement of the manimary glands in excess of the normal enlargement for pregnant rabbits was found with doses greater than or equal to 1.2 mg/kg/day (equal to the maximum human dose on a mg/m-basis). This effect occurred only in pregnant rabbits and regressed during lactation. Similar changes in the maininary glands were not observed in rats or monkeys.

There are no adequate and well controlled studies in pregnant women. It felodipine is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential hazard to the telus, possible digital anomalies of the infaut, and the potential effects of felodipine or labor and delivery, and on the infaut. and on the maminary glands of pregnant temales

Nursing Mothers

It is not known whether this drug is secreted in human milk and because of the potential for serious adverse reactions from felodipine in the infant, a decision should be made whether to discontinue nors ing or to discontinue the drug, taking into account the importance of the drug to the mother

Pediatric UseSafety and effectiveness in children have not been established

ADVERSE REACTIONS

In controlled studies in the United States and overseas approximately 3000 patients were treated with felodipine as either the extended release or the immediate release formulation.

The most common chinical adverse experiences reported with PLENDIL (Felodipine) administered as monotherapy in all settings and with all dosage forms of felodipine were peripheral edenta and headache. Peripheral edenta was generally indictive was age and dose related and resulted in discontinuation of therapy in about 4 percent of the enrolled patients. Discontinuation of the apply due to any clinical adverse experience occurred in about 9 percent of the frents receiving PLENDIL, principally for peripheral edema,

Adverse experiences that occurred with an incidence of 1.5 percent or greater during monotherapy with PLI NDB without regard to causality are compared to placebo in the table below.

Percent of Patients with Adverse Effects in Controlled Trials of PLENDIL as Monotherapy (incidence of discontinuations shown in parentheses)

Adverse Effect	PLENDIL' N = 730	
Peripheral Edema	22.3 (4.3	
Headache	18.6 (2).	
Hushing	64 (10	
Dizziness	5.8 (0.8	3.2
Opper Respiratory		
Intection	5.5 {0.	
Asthenia	4 / (0	
Cough	2.9 (0.0	
Paresthesia	2.5 (0	
Dyspepsta	2.3 (0.1	
Chest Pam	2.1 (0)	
Nausea	1.9 (0.3	
Muscle Cramps	1.9 - (0.1)	
Palpitation	1.8 (0):	
Abdominal Pain	1.8 (0)	
Constipation	1.6 (0.	
Diarrhea	1.6 (0.	
Pharyngitis	1.6 - (0.1	
Rhuorrhea	1.6 - (0.1	
Back Pain	1.6 (0)	
Rash	1.5 (0.	
	a distance of the	. DELIMINE thoras

The following Table describes the incidence (percent) of adverse expe-

riences that were dose related. The incidence of discontinuations adverse experiences

Adverse Effect	Placebo N = 121	2.5 mg N = 71	5.0 mg N = 72	10.0 mg N = 123	20 mg N = 50
Penpheral Edema	2.5 (1.6)	1.4 (0.0)	13.9 (2.8)	19.5 (2.4)	36.0 (10.0)
Palpitation	0.8 (0.8)	1.4 (0.0)	0.0 (0.0)	2.4 (0.8)	12.0 (8.0)
Headache	12.4 (0.0)	113 (14)	111(00)	18.7 (4.1)	28.0 (18.0)
Husting	0.0 (0.0)	4.2 (0.0)	2.8 (0.0)	8.1 (0.8)	20.0 (8.0)

In addition, adverse experiences that occurred in 0.5 up to 1.5 percent of patients who received PLENDIL. (Felodipine) in all controlled clinical studies (listed in order of decreasing severity within each category) and serious adverse events that occurred at a lower rate or were found during marketing experience (those lower rate events are in Italics) were: Body as a Whole. Facial edema, warm sensation Cardiovascular. Tachycardia, injocardial infarction, hypotension, syn cope, angina pectoris, arrhythmia; Digestive: Vomiting, dry mouth rope, angua pecinis, arriyumna, bigestie, vanining, ar yusun, flatulence, Hematologic, Anema, Musculoskeletal, Arthralgia, arm pain, knee pain, leg pain, foot pain, lip pain, myalgia, Nervous/Psychiatric. Depression, anxiety disorders, insomnia, irritability, nervousness, somnolence, Respiratory Bronchitis, influenza. sinusifis, dyspinea, epistaxis, respiratory infection, sneezing. Sim. Confusion, erythema, urticaria, Urogenital: Decreased libido, nipo tence, urmary frequency, urmary urgency, dysuria.

felodipme, as an immediate release formulation, has also been studied as monotherapy in 680 patients with hypertension in U.S. and overseas controlled clinical studies. Other adverse experiences not listed above and with an incidence of 0.5 percent or greater include. *Body as a Whole*: Fatigue: *Digestive*: Gastrointestinal pain: *Musculoskeletal*: Arthritis, local weakness, neck pain, shoulder pain. ankle pam. Nervous/Psychiatric Tremor Respiratory Rhindlis, Skin Hyperhidrosis, printlus, Special Senses, Bluried vision, fumitus, Urogenital: Noctura

Gingival Hyperplasia: Gingival hyperplasia, usually mild, occurred m - 0.5 percent of patients in controlled studies. This condition may be avoided or may regress with improved dental hygiene. (See PRE-CAUHONS, Information for Patients.)

Clinical Laboratory Test Findings
Serum Electrolytes: No significant effects on serum electrolytes were observed during short and long term therapy.
Serum Glucose: No significant effects on fasting serum glucose were observed in patients treated with PLENDIL in the U.S. controlled.

Liver Enzymes: One of two episodes of elevated serum transaminas-es decreased once drug was discontinued in clinical studies; no follow up was available for the other patient

OVERDOSAGE

Oral doses of 240 mg/kg and 264 mg/kg in male and female mice, respectively and 2390 mg/kg and 2250 mg/kg in male and female rats, respectively caused significant lethality.

In a suicide attempt, one patient took 150 nig telodipine together with 15 tablets each of atenefol and spironolactore and 20 tablets of intrazepain. The patient's blood pressure and heart rate were normal on admission to hospital; he subsequently recovered without significant sequelae

Overdosage inight be expected to cause excessive periphera vasudilation with marked hypotension and possibly bradycardia

If severe hypotension occurs, symptomatic treatment should be instituted. The patient should be placed supme with the legs ele-vated. The administration of intravenous fluids may be useful to freat hypotension due to overdosage with calcium antagonists. case of accompanying bradycardia, alreptic (6.5 f. mag) should be administered intravenously. Sympathonimetic drugs may also be given if the physician feels they are warranted.

It has not been established whether telodipine can be removed from the circulation by hemodialysis

DOSAGE AND ADMINISTRATION

The recommended unitial dose is 5 mg once a day. Therapy should the recommendate unitar costs is a ling since a vary measily shown be adjusted individually according to patient response, generally at intervals of not less than two weeks. The usual dosage range is 5 10 mg once daily. The maximum recommended daily dose is 20 mg once a day. That dose in clinical trials showed an increased blood pressure response but a large increase in the rate of peripheral edeina and other vasied data of the weak of the control of t HONS) Modification of the recommended dosage is usually not required in patients with renal impairment.

PLENDIL should be swallowed whole and not crushed or chewed.

Use in the Elderty or Patients with Impaired Liver Function. Patients over 65 years of age or patients with impaired liver function Fatients over our years of age of maneins with opportunities of account because they may develop higher plasma concentrations of telodic pine: should have their blood pressure monitored closely during dosage adjustment (see PRECAUTIONS). In general, doses above 10 mg should not be considered in these patients.

A/M GROUP

For more detailed information, consult your Astra/Merck Specialist or see complete Prescribing Information. Astra/Menck Group of Merck & Co., Inc 725 Chesterbrook Boulevard, Wayne, PA 19087

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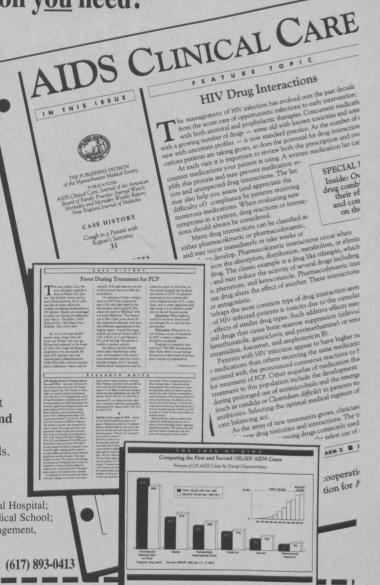
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The vast majority of patients on PLENDIL receive prescriptions for 5 mg, once daily.*

PLENDIL provides a gradual onset of action for continuous 24-hour blood-pressure control in many patients.

And, PLENDIL is suited to a broad range of your hypertensive patients — including many with concomitant disorders, such as: hypercholesterolemia, diabetes, impaired renal function, COPD, or asthma.

PLENDIL. A highly effective calcium channel blocker for blood pressure control. Generally well tolerated at usual doses.[†]



Plendil

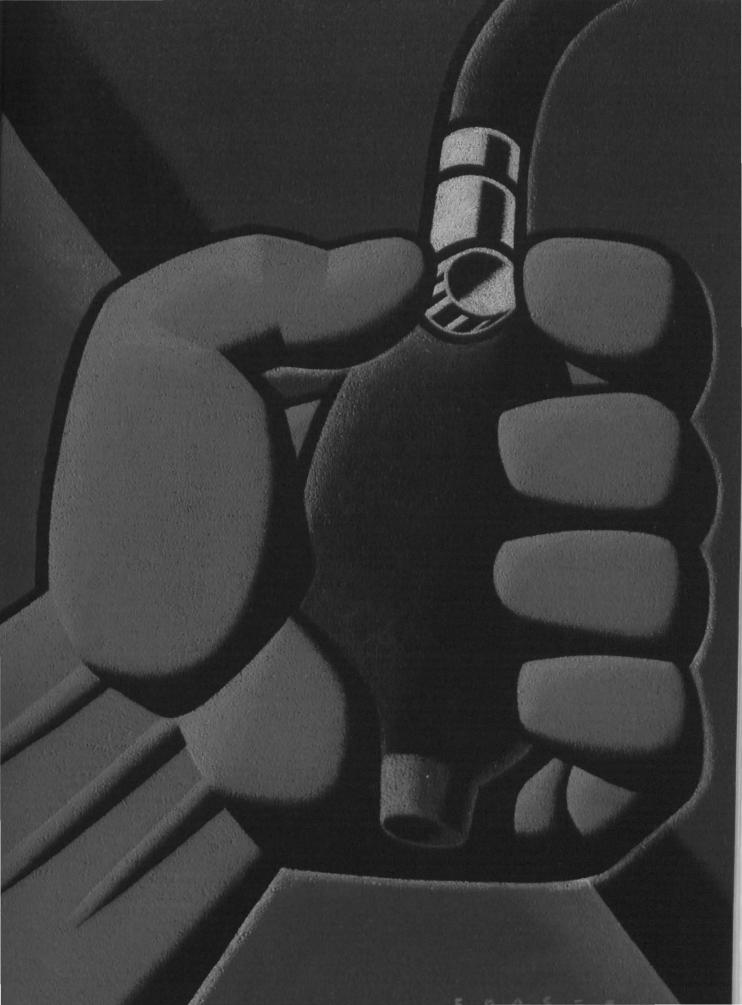
(felodipine) Tablets, 5 mg, 10 mg

Because you consider the whole patient.

*1993 IMS NDTI Prescription Data.

Peripheral edema, generally mild, was the most common adverse event in clinical trials.

PLENDIL is contraindicated in patients who are hypersensitive to this product. Please see brief summary of Prescribing Information on page following next page.



BRIEF SUMMARY

PLENDIL" (FFLODIPINE)

EXTENDED RELEASE TABLETS

INDICATIONS AND USAGE

his indicated for the treatment of hypertension, PTTNDB may be used alone or concountantly with other authypertensive agents

CONTRAINDICATIONS

PLENDIE is contraindicated in patients who are hypersensitive to this product

PRECAUTIONS

General

Hypotension: Lelodipme, like other calcium antagonists, may occainforcement, reacquer use a requirement and carely synope. It may lead to relies factor, and which in susceptible individuals may precipitate angus pectors. (See ADVLRSE REAGIONS.)

heart Failure. Although acute bemodynamic studies in a small mumber of patients with NYIA Class. If or 31 heart failure heated with felodipone have not demonstrated negative motiopic effects, safely in patients with heart failure has net been established. Cambon there fore should be exercised when using PT NOIE in patients with heart. failure or compromised ventocular function, particularly in combins tion with a beta blocker

Elderly Patients or Patients with Impaired Liver Function: Patients cherry alens of age or patients with imparted liver function may have clevated plasma concentrations of teledipine and may therefore respond to lower doses of PELNOT. These patients should have their blood pressure monitored closely during disage adjustment of PELNOT and should ranely require doses show 10 mg. Ose CHINICAL PHARMACOLOGY and DOSAGLAND ADMINISTRATION sections of some plete Prescribing Information)

Peripheral Edema: Peripheral edema: generally mild and not asso-ciated with generalized Huid retention, was the most common adverse event in the clinical trials. The incidence of peoplieral edenia was both dose, and age dependent. Lucquency of peripheral edicina ranged from about 10 percent in patients moler 50 years of age taking 5 mg daily to about 30 percent in those over 60 years of age taking 20 mg. daily. This adverse effect generally occurs within 2.3 weeks of the ini-

Information for Patients

Information for Patients

Patients should be instructed to take PTENDH whole and not to crush or chew the tablets. They should be told that and progreat hyperplasta (gun swelling) has been reported. Good deutal hygenedecreases its incidence and severily.

NOTE: As with many other days, certain advice to patients being freal ed with PLNOR is warranted. This information is intended to aid in the safe and effective rise of this medication. If is not a disalosme of all possible adverse or intended effects.

Drug Interactions
Beta Blocking Agents: A pharmacokinetic study of felodipine in
committee with inelograted demonstrated no significant effects on
the pharmacokinetics of felodipine. The ARC and Grass of metoprolol. me paramaconica, su casada piposenately 31 and 38 percent respec-tively. In controlled clinical tradic bowever, beta blocker, including inclupiolid were concurrently administered with teledipute and were

Cimetidine: In healthy subjects pharmacokinetic studies showed an Communities of the carmy singles printing outer a source and approximately 50 percent increase in the arm under the plasmos can contration time curve (AHC) as well as the Cona of belodiquies when given concombantly with conceive. It is adopted that a clinical by significant interaction may occur in some hypertensive patients. Bierchare, it is recommended that how doses of PLENDIL be used when given concomitantly with cimelidure

Digoxin: When given concountantly with telodipme the peak plasma concentration of digoxin was significantly increased. There was however, no significant change in the AUC of digoxin.

ever, no significant example in the Auto of original.

Anticonvolvants, be a planma observe sholy magnetim plasma
concentrations of felodipine were considerably lower in epileptic
patients and long-term authorizational therapy (e.g. phenylom carbo
magnetic or plasmbandral all than in beathy submittees). In such
patients, the mean area make indied the lebidipine plasma concentration
time curve was also reduced to approximately as percent of that
observed in the afthy solunteers. Since a clunically significant interation may be authorpated, alternative authopathersize therapy should
be considered in these patients.

Other Concentrat Therapide headility solunce. Those were made.

Other Concomitant Therapy: In healthy subjects There were no clin ically significant interactions when teledipine was given concoun-

Caulty with indicate that is a spinoriolist force.

Interaction with Food: See: CHNICAL PHARMAGOLOGY. Pharmago.

Interaction with Food: See: CHNICAL PHARMAGOLOGY. Pharmago.

Interaction with Food: See: CHNICAL PHARMAGOLOGY. Pharmago.

binder, and bletabolism action of complete Prevailing Information.

Carcinogenesis, Mutagenesis, Impairment of Ferthily.

In a two year carcinogenicity study in acts ted felodopine at doses of 1.1, 23.1 in 6.9.3 ing/kg/day (ng to 28 times, the maximum recommended human dose on a might beard, a dose related increase in the maderiac of being indestinat cell timors of the teste. It egylig cell timors, was observed in treated made rate. These timors was not end observed in a similar study in mice at doses up to 1.88 in ing/kg/day (28 times, the maximum recommended human dose in a nig/m baras). Telodopine, at the doses comployed in the two year rat. Judy, has, here shown to lower testional necknown and to produce a row. has been shown to lower testicular testosterone and to produce a cor-responding increase in serom luteroizing hormone in rats. The Feydig famor development is possibly secondary to these hormonal effects which have not been observed in man-

In this, tame rat study a dose telater increase in the inculence of local squamous cell hyperplasta compared to control was observed in the exophageal groose of male and lonate rats in all dose groups. No other drug related esophageat or gastric pathology was observed in the rats in with chronic administration in ince and dog. The latter

species, like man, has no anatomical structure comparable to the esophageal groove

Felodique was not carcinogenic when hed to mice at doses of up to 138.6 mg/kg/day (28 times, the maximum recommended limitan dose on a mg/m. basic) for periods of up to 80 weeks in males and 99

reladipme did not display any umbagenic activity *m vitro* in the Ames uncolord analogenicity test or in the minist lymphonia loward analom assay. As classing in potential was seen *m vivo* in the purse micronicidens fest at oral disses up to 7500 mp/g (506 times the maximum recommended human dose on a mg/m basis) or *m vitro*. in a human lymphocyte chroniosome aberration assay

A terbity sludy in which male and temale rats were administered dozes of 3.8, 9.6 or 25.9 mg/kg/day showed no significant effect of telodipine on reproductive performance

Preenancy

Pregnancy Category C

Tecathgram Effects Studies in pregnant rabbits administered doses of 0.46, 1.2, 2.3 and 4.6 mg/kg/day (from 0.4 to 4 times. The maximum recommended human dose on a mg/m. basis) showed digital anomrecommended minian dose on a nigrin massy showed nigran amon-alies consisting of reduction in size and degree of ossistation of the ter-minal phalanges in the februse. The frequency and severity of the changes appeared dose related and were noted even at the lowest dose. These changes have been shown to occur with other members of the dihydropyrdine class and are possibly a result of compromised atorine blood flow. Similar fetal anomalies were not observed in rats given telodipine.

In a teratology study in cynomolgus monkeys no reduction in the size of the terminal phalanges was observed but an abnormal position of the distal phalanges was noted in about 40 percent of the fetuses.

the instal pharmages was noted in about 40 partention with dilucuil Monteratogenic Effects. A prolongation of partinition with dilucuil labor and an increased frequency of letal and early octuated deaths were observed at rats administered dozes of 9.6 mg/log/day (4 lines the maximum human doze on a mg/m-basis) and above.

argumean caragement for program cubbits was found with doses greater than or equal to 12 mg/kg/day/tegual to the maximum human dose on a mg/m-basis). This effect occurred only in program cabbits and regressed during lactation. Similar changes in the manionary glands were not observed in rats or monkeys

grams were no nealeguale and well controlled studies to pregnant wance. If felodipine is used during pregnancy, or if the patient becomes pregnant while taking flar drug, she should be appressed of the polential hazard to the fetus, possible digital anomaties of the infant, and the potential effects of felodipine on labor and delivery, and on the manurary glands of pregnant females.

Nursing Mothers

It is not known whether this drug is secreted in banian unlik and because of the potential for senous adverse reactions from felodipine in the infant, a decision should be made whether to discontinue nors ing or to discontinue the drug, taking into account the importance of

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

in controlled studies in the United States and overseas approxi-mately 3000 patients were treated with felodomic as either the extended release or the numedrate release formulation

The most common clinical adverse experiences reported with PELNOR: (Lelodypine) administered as monotherapy in all settings and with all dosage torms of felodypine were peripheral edemia and and with an rowage turns of recorpine were peripheral edema and heradache. Peripheral edema was generally mild, but it was age, and dose related and resulted in discontinuation of therapy in about 4 percent of the enrolled patients. Biscontinuation of therapy doe to any clinical adverse experience occurred in about 9 percent of the patients, receiving PH MILL principally for peripheral edema, loodically at the bins. beadarthe or flushing

Adverse experiences that occurred with an incidence of 1.5 percent or greater during monotherapy with PELNDIL without regard to causality are compared to placelio in the table below

Percent of Patients with Adverse Effects in Controlled Trials of PLENDIL as Monotherapy (incidence of discontinuations shown in parentheses)

Adverse Effect	PLENDIL% N = 730	Placebo % N = 283	
Perpheral Edema	22.3 (4.2)	3 5	
Headache	186 (21)	10.6	
Husbing	6.4 (1.0)	11	
Dizzmess	5.8 (0.8)	3.7	
Upper Respiratory			
Infection	5.5 (0.1)	1.1	
Asthenia	47 - (0.1)	2.8	
Cough	2.9 (0.0)	0.4	
Paresthesia	2.5 (0.1)	1.8	
Dyspepsia	2.3 (0.0)	1.4	
Chest Paur	2.1 (0.1)	1.4	
Namea	1.9 (0.8)	1.1	
Muscle Comps	19 (0.0)	1.1	
Palpitation	18 (0.5)	2.5	
Abdominal Pani	1.8 (0.3)	1.1	
Constipation	16 (04)	1.1	
Drarchea	1.6 (0.1)	1.1	
Pharyingths	16 (0.0)	0.4	
Rhijjarhea	1.6 (0.0)	0.0	
Back Patit	16 (0.0)	1.1	
Rash	1.5 (0.1)	1.1	

In the two dose response studies using PTINDII as monotherapy the following table describes the incidence (percent) of adverse expe

riences that were dose related. The incidence of discontinuations due to these adverse experiences are shown in parentheses

Adverse Effect	Placebo N = 121	2.5 mg N = 71	5.0 mg N = 72	10.0 mg N = 123	20 mg N = 50
Peripheral Edema	2.5 (1.6)	14 (0.0)	13.9 (2.8)	19.5 (2.4)	36,0 (10.0)
Palpitation	0.8 (0.8)	1.4 (0.0)	0.0 (0.0)	2.4 (0.8)	120 (80)
Headache	12.4 (0.0)	11.3 (1.4)	$11 \pm (0.0)$	18 7 (4.1)	28.0 (18.0)
Husbing	0.0 (0.0)	4.2 (9.9)	2.8 (0.0)	8.1 (0.8)	20.0 (8.0)

In addition, adverse experiences that occurred in 0.5 up to 1.5 pe cent of patients who received PTENDII. (Felodipine) in all controlled chinical studies (listed in order of decreasing severily within each cat egory) and scrious adverse events that occurred at a lower rate or were found during marketing experience (those lower rate events are in (talics) were: Body as a Whole, Lacial edenia, warm sensation, Cardiovascular Tachycardia, myocardial infanction, hypotension, syn Catanyasachi (attiyaatii), nijocantari minictan, nipoteissiai, syn-cope, anguri pecloris artiyllimia, Digestive Voniding, diy nonlih Balulence, Hematologie, Amenia, Muscaitoskeletal, Adhiralgia, ann pain, kine pain, leg pain, hod pain, lup pain, myalgia; Nervous/Psychiatric, Depression, anxiety disorders, insonnia, ori tability, nervousness, somnolence, Respiratory: Bronchitis, influenza,

smuratis, dyspuea, epistacis, respiratory infection, sneezing, Skin-Gaithesion, erythema, inficaria, Hogenital begreised libido, impotence, inmary frequency, orinary ingency, dysaira. Felodipine, as an animediate release formulation, has also been studied as monotherapy in 680 patients with hypertension in U.S. and overseas controlled clinical studies. Other adverse experiences not listed above and with an incidence of 0.5 percent or greater include. Budy as a Whole: Edipine, Digestive Gastrontestinal pain, Muscadoskeletal Arthoris, local weakness, neck pain. Similer pain, aikle pain. Networs/Psychiatric, Termir, Respiratory Rhinatis, Skin Eyperhidosys, printites, Special Seases, Blorod vision, fromtos, Hogenital Noclinia.

Gingival Hyperplasia: Gingival typerplasia, usually mild, occurred in + 0.5 percent of patients in controlled studies. This condition may be avoided or may regress, with improved dental laguene. (See PRI CAUTIONS, Information for Patients.)

Clinical Laboratory Test Findings

Control Laboratory test Findings Serum Electrolytes: No significant effects on serion electrolytes were observed doing short, and long bene therapy. Serum Glucose: No significant effects on fasting serion glucose were observed in patients treated with PTFNDH in the U.S. controlled

Liver Enzymes: One of two opnodes of elevated serum transammas es decreased once drug was discontinued in clinical studies, no follow up was available for the other patient

OVERDOSAGE

Oral doses of 240 mg/kg and 264 mg/kg in male and female male, respectively and 2390 mg/kg and 2250 mg/kg in male and female rats, respectively, caused significant felliality.

in a smooth attempt, one patient hook 150 mg teledipore together with 35 tablets each of atended and spironolastone and 20 tablets of intrazepain. The patient's blood pressure and heart rate were normal on admission to hospital, be subsequently recovered without significant semielae

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly bradycardia

It severe hypotension occurs symptomatic freatment should be instituted. The patient should be placed supine with the legs ele-vated. The administration of intravenous fluids may be useful to varier — the administration of incoverdosage with calcium antagonists in heast hypotension due to overdosage with calcium antagonists in case of accompanying bradycardia, alropine (0.5.1 mg) should be administered intravenously. Sympathoniumetric durgs may also be given if the physician feels they are warranted.

It has not been established whether telodipme can be removed from the circulation by hemodralysis

DOSAGE AND ADMINISTRATION

The recommended initial dose is 5 ing once a day. Therapy should The recommended until doze is 5 mg after a day true-ray about the adjusted individually according to patient tesponase generally at intervals of not less than live weeks. The transit do age range is 5 to nig once daily. The maximum recommended daily doze is 28 mg once a day. That doze in climical trials showed an increased blood pressure response but a large increase in the rate of pempleral referral and other visualisation, adverse events foce ADVERSE R ACTIONS). Modification of the recommended dosage is usually not required in potents, with renat improvings.

[8] ENDL Solvid but we sufficient winder and full cruched or chewrot.

PLENDIL should be swallowed whole and not crushed or chewed.

Use in the Elderly or Patients with Impaired Liver Function: Patients over 65 years of age or patients with impaired liver function. orders over a system an age of parameter word infigured fiver final because they may develop higher plasma concentrations of folding, should have their blood pressure monitored closely during disage adjustment (see PRI CAHRONS). In general, doses above 10 mg should not be considered in these patients.

A/M GROUP

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From a unique chemical class of non-benzodiazepine sleep agents

More sleep

Total sleep time is significantly increased compared with placebo. Patients fall asleep quickly; generally within 20 to 30 minutes. 1-3

Better sleep

Awakenings were reduced, compared to placebo.

Through the night

No evidence of increased wakefulness during the last third of the night. Normal sleep stages are generally preserved (clinical significance unknown).

With no objective evidence of tolerance or rebound insomnia

In studies of up to 35 consecutive nights at recommended doses. 12

Favorable safety and tolerability profile Adverse events with dosages of ≤ 10 mg that were statistically significant vs placebo

Short-term: ≤10 nights		hts Long-term: 28 to 35 n	
drowsiness	2%	dizziness	5%
dizziness	1%	drugged	
diarrhea	1%	feelings	3%



In the short-term treatment of insomnia

First in a unique chemical class of non-benzodiazepine sleep agents



BRIEF SUMMARY

INDICATIONS AND USAGE

Ambien (zolpidem tarirate) is indicated for the short term freatment of insomma. Hypotics should generally be limited to 7 to 10 days of use, and revaluation of the patient is recommended if they are to be taken for more than 2 to 3 weeks.

Ambien Should not be prescribed in quantities exceeding a 1-month supply (see Warnings).

CONTRAINDICATIONS

WARNINGS

WARNINGS

Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomain should be initiated only after a careful evaluation of the patient. The failure of insonnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or inedical illness which should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including Ambien. Because some of the important adverse effects of Ambien appear to be dose related (see Precoutions and Dosage and Administration), it is important to use the smallest possible effective dose, especially in the eldery-been. A variety of abnormal timeking and behavior changes hypnotics. Some of these changes may be characterized by decreased inhibition (eg., aggressiveness and extroversion that seemed out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bytarre behavior, agitation, hallucinations, and depensionalization. Amnesia and other europsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of seature/hypnotics.

It can rarely be determined with certainty whether a particular

ing, has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above are drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation. Following the rapid dose decrease or abrupt discontinuation of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs (see Drug Abuse and Dependence).

Ambien, like other sedative/hypnotic drugs, has CNS-depressant effects Due to the rapid onset of action, Ambien should only be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of Ambien. Ambien showed additive effects with other CNS-depressant drugs. Dosage adjustments may be necessary when Ambien is administered with such agents because of the potentially additive effects.

PRECAUTIONS

PRECAUTIONS

General

Use in the elderly and/or debilitated patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. Therefore, the recommended Ambien dosage is 5 mg in such patients (see Dosage and Administration) to decrease the possibility of side effects. These patients should be closely monitored.

Use in patients with concomitant illness: Clinical experience with Ambien in patients with concomitant systemic illness is limited. Caution is advisable in using Ambien in patients with diseases or conditions that could affect metabolism or hemodynamic responses. Although preliminary studies did not reveal respiratory depressant effects at hypnotic doses of Ambien in normals, precautions should be observed if Ambien is prescribed to patients with compromised respiratory function, since sedative/hypnotics have the capacity to depress respiratory drive. Post-marketing reports of respiratory increases of the patients with pre-existing reports accompliation or alterations in pharmacokinetic parameters. No dosage adjustment in renally impaired patients is required however, these patients should be closely monitored (see Pharmacokinetics). A study in subjects with hepatic impairment should be initiated with 5 mg in patients with hepatic impairment, and they should be closely monitored.

monitored. Use in depression: As with other sedative/hypnotic drugs, Ambien should be administered with caution to patients exhibiting signs or symptoms of depression. Suicidal tendencies may be present in such patients and protective measures may be required, Intentional overdosage is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information for patients: Patient information is printed in the complete prescribing information and is available in pads for distribution to patients.

Laboratory tests: There are no specific laboratory tests recommended

to patients
Laboratory tests: There are no specific laboratory tests recommended.
Drug interactions
CNS-active drugs: Ambien was evaluated in healthy volunteers in single-dose interaction studies for several CNS drugs. A study involving haloperidol and zolpidem revealed no effect of haloperidol on the pharmacokinetics or pharmacodynamics of zolpidem. Impramine in combination with zolpidem produced no pharmacokinetic interaction other than a 20% decrease in peak levels of impramine, but there was an additive effect of decreased alertness. Similarly, chlor-promazine in combination with zolpidem produced no pharmacokinetic interaction, but there was an additive effect of decreased alertness. Similarly, chlor-promazine in combination with zolpidem produced no pharmacokalertness and psychomotor performance. The lack of a drug interaction following single-dose administration does not predict a lack following chronic administration.

An additive effect on psychomotor performance between alcohol and zolpidem was demonstrations of Ambien in combination with Since the systematic evaluations of Ambien in combination with since the systematic evaluations of Ambien in combination with should be given to the pharmacology of any CNS active drug to be used with zolpidem Any drug with CNS depressant effects of solpidem.

Other drugs: A study involving cometome zolpidem and rantidune/zolpidem combinations revealed no effect of either drug on the harmacokinetics or pharmacodynamics of zolpidem. Zolpidem had no effect on digoxin kinetics and did not affect prothrombin time when given with warfarm in normal subjects. Zolpidem's sedative/hypnotic effect was reversed by flumazeni!; however, no significant alterations in zolpidem pharmacokinetia solpidem is not known to interfere with commonly employed clinics were found.

Carcinogenesis: Zolpidem was administered to rats and mice for 2

terfere with commonly employed clinical laboratory tests. Carcinogenesis, mutagenesis, indigenesis, indigenesis, indigenesis, more for 2 carcinogenesis. Zolpidem was administered to rats and mice for 2 cears at deltary dosages of 4. 18. and 80 mg/kg/day. In mice, these doses are 26 to 520 times or 2 to 35 times the maximum 10-mg human dose on a mg/kg/or mg/m² basis, respectively. In rats these doses are 43 to 876 times or 6 to 115 times the maximum 10-mg human dose on a mg/kg/or mg/m² basis, respectively. No evidence of carcinogenic potential was observed in mice. Renal liposarcomas were seen in 4/100 rats (3 mailes. 1 female) receiving 80 mg/kg/day and a renal lipoma was observed in one male rat at the 18 mg/

kg/day dose. Incidence rates of lipoma and liposarcoma for zolpidem were comparable to those seen in historical controls and the tumor findings are thought to be a spontaneous occurrence.

findings are thought to be a spontaneous occurrence. Mutagenesis: Zolpidem did not have mutagenic activity in several tests including the Ames test, genotoxicity in mouse lymphoma cells in vitro, chromosomal aberrations in cultured human lymphocytes, unscheduled DNA synthesis in rat hepatocytes in vitro, and the micronucleus test in mice impairment of fertility: In a rat reproduction study, the high dose (100 mg base/kg) of zolpidem resulted in irragular estrus cycles and prolonged precortal intervals, but there was no effect on male or female fertility after daily oral doses of 4 to 100 mg base/kg or 5 to 130 times the recommended human dose in mg/m². No effects on any other fertility parameters were noted.

Pregnancy
Category B. Studies to assess the effects of zolpidem on human

Category B. Studies to assess the effects of zolpidem on human reproduction and development have not been conducted. Teratology studies were conducted in rats and rabbits in rats, adverse maternal and fetal effects occurred at 20 and 100 mg basek, gand included dose-related maternal lethargy and ataxia and a dose-related trend to incomplete ossification of fetal skull bones.

bones.
In rabbits, dose-related maternal sedation and decreased weight gain occurred at all doses tested. At the high dose, 16 mg base/kg, there was an increase in postmplantation fetal loss and underossification of sternebrae in vable fetuses.
This drug should be used during pregnancy only if clearly needed.

This drug should be used during pregnancy only it clearly needed. Nonteratogenic effects: Studies to assess the effects on children whose mothers took zolpidem during pregnancy have not been conducted. However, children born of mothers taking sedative/hyp-notic drugs may be at some risk for withdrawal symptoms from the drug during he postnatal period. In addition, neonatal flaccidity has been reported in infants born of mothers who received sedative/ hypnotic drugs during pregnancy. Labor and delivery: Ambien has no established use in labor and delivery.

delivery.

Nursing mothers: Studies in lactating mothers indicate that between 0.004 and 0.19% of the total administered dose is excreted into milk, but the effect of zolpridem on the infant is unknown.

The use of Ambien in nursing mothers is not recommended. Safety and effectiveness in children below the age of 18 have not been established.

ASSociated with discontinuation of treatment: Approximately 4% of 1,701 patients who received zolpidem at all doses (1.25 to 90 mg) in U.S. premarketing clinical trials discontinued treatment because of an adverse clinical event. Events most commonly associated with discontinuation from U.S. trials were daytime drowsiness (0.5%), dizznass (0.4%), headache (0.5%), nausea (0.6%), and vomitting (0.5%).

(0.5%) Approximately 6% of 1,320 patients who received zolpidem at all doses (5 to 50 mg) in similar foreign trials discontinued treatment because of an adverse event. Events most community associated with discontinuation from these trials were daytime drowsiness (1.6%), amnesia (0.6%), dizziness (0.6%), headache (0.6%), and nausa (0.6%).

Incidence in controlled clinical trials.

Incidence in controlled clinical trials Most commonly observed adverse events in controlled trials: During short-term treatment (up to 10 nights) with Ambien at dose up to 10 mg, the most commonly observed adverse events associated with the use of zolpidem and seen at statistically significant differences from placebo-treated patients were drowsness (reported by 2% of zolpidem patients), dizziness (11%), and diarrhea (11%). During longer-term treatment (28 to 35 nights) with zolpidem at doses up to 10 mg, the most commonly observed adverse events associated with the use of zolpidem and seen at statistically significant differences from placebo-treated patients were dizziness (5%) and drugged feelings (3%).

Incidence of Treatment-Emergent Adverse Experiences in Short-term Placebo-Controlled Clinical Trials (Percentage of patients reporting)

Body System/ Adverse Event*	Zolpidem (≤ 10 mg) (N=685)	Placebo (N=473)
Central and Peripheral Nervous System		
Headache	7	6
Drowsiness	2	-
Dizziness	1	-
Gastrointestinal System		
Nausea	2	3
Diarrhea	1	-
Musculoskeletal System		
Mvalgia	1	2

Events reported by at least 1% of Ambien patients are included.

Incidence of Treatment-Emergent Adverse Experiences in Long-term Placebo-Controlled Clinical Trials (Percentage of patients reporting)

Zolpidem

Body System/ Adverse Event*	(∴ 10 mg) (N=152)	Placebo (N=161)
Autonomic Nervous System		
Dry mouth	3	1
Body as a Whole		
Allergy	4 3 2 1	1 2
Back pain	3	2
Influenza-like symptoms		_
Chest pain		2
Fatigue	'	2
Cardiovascular System	•	
Palpitation	2	-
Central and Peripheral Nervous System		
Headache	19	22
Drowsiness	Ř	5
Dizziness	8 5 3 2 2 1	5 1 1
Lethargy	3	,
Drugged feeling	3	- 1 1
Lightheadedness	2	
Depression	2	
Abnormal dreams		_
Amnesia	i	
Anxiety	i	1 3
Nervousness	4	3
Sleep disorder	1	_
Gastrointestinal System		
Nausea	b	6
Dyspepsia	6 5 3 2 2 1	6 2 2 1 1
Diarrhea	3	2
Abdominal pain	2	
Constipation Anorexia	4	- 1
Vomiting	4	i
	,	
Immunologic System		
Infection	1	1
Musculoskeletal System	_	_
Myalgia	?	7
Arthralgia	4	4

Incidence of Treatment-Emergent Adverse Experiences in Long-term Placebo-Controlled Clinical Trials (Cont'd) (Percentage of patients reporting)

Body System/ Adverse Event*	Zolpidem (- 10 mg) (N=152)	Placebo (N : 161)
Respiratory System Upper respiratory infection	5	6
Sinusitis	ă	ž
Pharyngitis	3	1
Rhinitis	1	3
Skin and Appendages Rash	2	1
Urogenital System Urinary tract infection	2	2
*Events concreted by at least 1% of	entionts treated but	h Ambion

There is evidence from dose comparison trials suggesting a dose relationship for many of the adverse events associated with zolpidem use, particularly for certain CNS and gastrointestinal adverse events. Adverse events are further classified and enumerated in order of decreasing frequency using the following definitions: frequent adverse events are defined as those occurring in greater than 1/100 subjects; infrequent adverse events are those occurring in 1/100 to 1/1

patients; rare events are those occurring in less than 171,000 patients.
Frequent: abdominal pain, amnesia, ataxia, confusion, depression, darhea, diplopia, dizziness, dreaming abnormal, drowsiness, drugged feeling, dry mouth, dyspepsia, euphoria, fatigue, headache, insomina, ethargy, lightheadedness, myalga, nausea, upper respiratory infection, vertigo, vision abnormal, vomiting Infrequent: agitation, allergy, anorexia, anxiety, arthralgia, arthritis, asthenia, back pain, bronchitis, cerebrovascular disorder, chest pain, constipation, coughing, cystitis, decreased cognition, detached, difficulty concentrating, dysarthria, dysphagia, dyspinea, edema, emonal lability, eye irritation, falling, lever, flatulence, gastroententis, halucination, hiccup, hyperglycemia, hypertension, hyposethiesia, infection, influenza-like symptoms, malaise, menstrual disorder, mirritis, rash, thinitis, sclentis, SQPT increased, sinusitis, sleep disorder, sleeping (after daytime dosing), stupor, sweating increased, tackycardia, taste perversion, tinnitius, tooth disorder, rauma, tremor, unnary incontinence, urinary tract infection, viginitis.

sweating increased, tachycardia, taste perversion, tinnitus, tooth disorder, trauma, tereon, unnary incontinence, urinary tract infection, vaginitis.

Rare: abdominal body sensation, abscess, acne, acute renal failure, aggressive reaction, allergic reaction, allergy aggravated, anaphylactic stock, anemia, apportite increased, arrhythmia, artentis, arthrosis, biirubinemia, breast fibroardenosis, breast neoplasm, breast pain female, bronchospasm, bullous eruption, BUM increased, circulatory failure, sond processed, extrasystoles, eye pain, face edema, feeling strange, flushing, furunculosis, gastritis, glau-coma, gout, hemorrhoids, hepatic function abnormal, herpes simplex, herpes zoster, hot flashes, hypercholesteremia, hyperhemoglobinena, hypertension aggravated, hypotension, hypotenia, hypoxia, hysteria, iliusion, impotence, injection site inflammation, intestinal obstruction, intoxicated feeling, lacrimation abnormal, laryngitis, leg cramps, leukopenia, libido decreased, lymphadenopathy, neurosis, ottis externa, ottis media, pain, pain cattock, paress, personality disorder, philobitis, photospia, photosensitivity reaction, pneuronia, polyuria, pulmonary edema, pulmonary embolism, purpura, pyelionephritis, rectal hemorrhage, read pain restless legs, figora, empri, soncoe, tendinitis, tenesnus, tetany, thinking abnormal, thirist, tolerance increased, tooth cares, urinary retention, urticaria, varicose veins, ventricular tachycardia, weight decrease, yawning.

DRUG ABUSE AND DEPENDENCE

vancose veins, ventricular tachycardia, weight decrease, yawning.
DRUG ABUSE AND DEPENDENCE

Controlled substance: Schedule IV.

Abuse and dependence: Studies of abuse potential in former drug abusers found that the effects of single doses of zolpidem tartrate 40 mg were similar, but not identical, to diazepam 20 mg, while zolpidem tartrate 10 mg was difficult to distinguish from placebo. Sedative/hypnotics have produced withdrawal signs and symptoms following abrupt discontinuation. These reported symptoms range from mild dysphoria and insomnia to a withdrawal syndome that may include abdominal and muscle cramps, vomiting, swesting, temors, and convulsions. The U.S. clinical trial experience from zolpidem does not reveal any clear evidence for withdrawal syndome. Nevertheless, the following adverse events included in DSM-III-R criteria for uncomplicated sedative/hypnotic withdrawal were reported at an incidence of ≤ 195 duning U.S. clinical trials following placebo substitution occurring within 48 hours following last zolpidem treatment: fatigue, nausea, flushing, lightheadedness, uncontrolled crying, emesis, stomach cramps, panic attack, nervousness, and abdominal discomfort. Individuals with a history of addiction to, or abuse of, drugs or alcohol are at risk of habituation and dependence; they should be under careful surveillance when receiving any hypnotic.

OVERDOSAGE

under careful surveillance when receiving any hypnotic.

OVERDOSAGE

Signs and symptoms: In European postmarketing reports of overdose with zolpidem alone, impairment of consciousness has ranged
from somnolence to light coma, with one case each of cardiovascular
and respiratory compromise. Individuals have fully recovered from
complete and trate overdoses up to 400 mg (40 times the maximum
recommended dose). Overdose cases involving multiple CNS depressant agents, including zolpidem, have resulted in more severe symptomatology, including fatal outcomes.

Recommended treatment: General symptomatic and supportive
measures should be used along with immediate gastric lavage where
appropriate intravenous fluids should be administered as needed
flumazenii may be useful. Respiration, pulse blood pressure, and
other appropriate signs should be monitored and general supportive
measures employed. Sectaing drugs should be withheld following
Top possibility of multiple drug ingestion should be considered.
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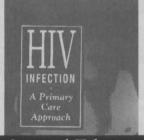
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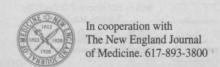
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— New London Hospital seeks a board certified/ eligible Family Practitioner for growing, exciting group practice opportunity. Excellent salary, liberal vacation and CME benefit package. The hospital is in excellent financial position for the future. We are close to major medical teaching facilities yet still retain the New England small town charm. The New London/Lake Sunapee area of New Hampshire is rated one of the most attractive in New England. We enjoy the four seasons with skiing, boating, hiking and other outdoor activities. Please forward resume to: Ray Bonito, Vice President for Ambulatory and Professional Services, New London Hospital, 270 County Road, New London, NH03257.

MAINE — Superb FP opportunity now available on Maine's southern seacoast. Global practice includes lab, x-ray, physical therapy, endoscopy and more. Excellent salary plus bonus and professional expenses. Comprehensive benefits. Two years to partnership. One-in-four call coverage. OB would be essential. Enjoy boating, salling, skiling, golf, culture, shopping in this midsized coastal community. Just 25 miles to Portland and 90 minutes to Boston. For further details send CV in confidence to: Jonathan Shill, MD, The Medical Group, 3 Meadows Lane, Kennebunk, ME04043 or call: 207-985-7174.

NEW JERSEY'S DELIGHTFUL BERGEN COUNTY — Exceptional opportunity for BC/BE Family Practitioner to join five-physician group in a charming suburban community only thirty minutes from New York City. Complete lab, x-ray and surgical facilities. Guaranteed income leading to potential partnership. Contact: John C. Rogers, Medical Management Associates, 102 South Maple Avenue, Ridgewood, NJ 07450. Call: 201-444-2144.

LEADERSHIP/SUPERVISORY OPPORTUNITY ---

Coastal Southern Maine, for experienced BC Family Practitioner to work in one of five multispecialty health center locations. Join largest primary care group in state. Enjoy nearby ocean, mountains and lakes, plus cultural and college-town amenities. Progressive environment with emphasis on managed care offers teamwork, reasonable working hours, 1:4-5 call. Financial security of competitive salary, incentive bonus plan, excellent benefits package. Satisfy family needs for excellent education and safety of small city living with easy commute to Portland. Great skiing, sailing, hiking and more. Wonderful place to raise your children. Please call or send CV to: Renee Campbell, Provider Recrultment, Martin's Point Health Care Centers, PO Box 9746, Portland, ME 04104-5040, 800-348-9804.

COASTAL SOUTHERN MAINE & NEW HAMPSHIRE

- Largest primary care group in Maine expanding — seeks additional BC/BE family practitioners in several of five multispecialty health center locations in Maine and NH. Enjoy nearby ocean, mountains and lakes, plus cultural and academic amenities. rogressive environment with emphasis on managed care offers teamwork, reasonable working hours, 1:4-5 call. Financial security of competitive salary, incentive bonus plan, excellent benefits package. Satisfy family needs for excellent education and safety of small city living with easy commute to Portland and Boston. Great skiling, salling, hiking and more. Wonderful place to raise your children. Please call or send CV to: Renee Campbell, Provider Recruitment, Martin's Point Health Care Centers, PO Box 9746, Portland, ME 04104-5040, 800-348-9804.

WESTCHESTER COUNTY, NEW YORK — BE/BC FP for busy family medicine practice. Lucrative compensation package. Send CV to: Jules Ehrenberg, E.J. Michaels, 1865 Palmer Avenue, Larchmont, NY 10538. Call: 914-833-1700 ortoli-free outside the New York metropolitan area at: 800-333-2999, Fax: 914-833-1711.

SOUTHWESTERN CONNECTICUT — FAMILY PRACTICE — HOSPITAL GUARANTEE — Lucrative private practice offer. Contact: Mimi Kozma, VP, E.J. Michaels, Ltd., 1865 Palmer Avenue, Suite 101, Larchmont, NY 10538. Or call: 914-833-1700 or 800-333-2999 outside the NY metropolitan area. Orfaxyour CV to: 914-833-1711.

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AND SCRANTON/WILKES-BARRE, PENNSYLVANIA
— BE/BC Family Practitioners sought for hospital-

based and private practice positions. Outstanding compensation. Send CV: Shelley Carhill, E.J. Milchaels, Ltd., 1865 Palmer Avenue, Suite 101, Larchmont, NY 10538. Phone: 914-833-1700 or 800-333-2999 (outside NY metropolitan area). Fax: 914-833-1711.

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INTERNIST/FAMILY PRACTITIONER — BC/BE, Interest in purchasing existing practice in Northeastern Pennsylvania. Excellent potential. Financial assistance may be available for the practice as well as relocation. Reply Box 10197, JABFP.

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TEMPLE UNIVERSITY SCHOOL OF MEDICINE -CHAIRPERSON OF FAMILY PRACTICE AND COM-MUNITY HEALTH - Temple University School of Medicine is seeking a Chairperson for its Department of Family Practice and Community Health. Applicants for this full-time position must have board certification; academic experience with auglifications for appointment as Full Professor; demonstrated excellence in education and patient care; outstanding interpersonal and leadership skills; the ability to develop strong clinical/academic programs and to maintain effective ongoing associations with the institutions and practices essential to our required clinical clerkship; the knowledge and skills to develop and sustain a competitive residency program. Applicants should send their resumes and bibliographies to: Ms. Betty E. Berdel, Secretary to the Family Practice Search Committee, Office of the Dean, Temple University School of Medicine, 3420 North Broad Street, Philadelphia, PA 19140. Temple is an Affirmative Action/Equal Opportunity Employer and strongly encourages applications from women and minorities.

Southeast

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TYLER & COMPANY — Is seeking an MD for the position of Executive Vice President, Clinical Services for SunHealth Alliance, whose corporate offices are located in the growing progressive southeastern city of Charlotte, North Carolina. Please contact: Robin Singleton at 800-883-8803 or fax CV to 404-396-6693. All inquiries are confidential.

RESIDENCY DIRECTOR, DEPARTMENT OF FAMILY MEDICINE — MEDICAL UNIVERSITY OF SOUTH CAROLINA, CHARLESTON, SOUTH CAROLINA —

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CITY" — No cali/full-time scheduled hours for a board certified Family Practice or Internal Medicine Physician. St. Luke Hospital West is a 177-bed facility located twelve miles from downtown Cincinnati in Florence, Kentucky. We are seeking a staff physician whose duties will include responding to emergencies, and performing employee health and occupational medicine services. Compensation: \$117+k plus comprehensive benefit package. Please respond in confidence to: Brenda Ziegler, Physician Recruiter 800-345-7151, extension 3361 or fax: 606-572-3369.

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TOLEDO, OHIO — Family Practice, BC/BE FP for group practice. One-in-three coverage. Outstanding salary and benefits. Send CV to: Jules Ehrenberg, E.J. Michaels, 1865 Palmer Avenue, Larchmont, NY 10538. Call: 914-833-1700. Outside the NY metropolitan area: 800-333-2999. Fax: 914-833-1711.

DANVILLE/CHAMPAIGN-URBANA AREA, ILLINOIS — BE/BC FP sought for three-physician practice. One-in-three coverage; high income potential. Send CV: E.J. Michaels, Ltd., 1865 Palmer Avenue, Suite 101, Larchmont, NY 10538. Phone: 914-833-1700, 800-333-2999 (outside NY metropolitan area), Fax: 914-833-1711.

FAMILY PRACTICE — Group of three is looking for a fourth. Salary of \$130,000 with \$20,000 sign-on bonus and full benefits. Great family community with arts, theatre and symphony forty minutes away in Northwestern Illinois. For more information call: Durham Medical Search, Inc., 6300 Transit Road, PO Box 478, Depew, NY 14043. 800-633-7724 (USA), 800-367-2356 (NYS), 716-681-7408 (FAX).

110-PHYSICIAN MIDWEST MULTISPECIALTY — BC/BE candidates: dermatology, family medicine, pulmonology. Fourteen-county area healthcare center, draw over 320,000. Guaranteed salary first two years. Thriving family community. Purdue University offers academics, cultural events, Big 10 sports. Contact: Physician Recruitment, Arnett Clinic, PO Box 5545, Lafayette, IN 47904. 800-899-8448.

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Ask for operator 36.



MICHIGAN — War Memorial Hospital in Sault Ste. Marie, Michigan is assisting a well-respected, board certified FP in our community in the recruitment of a board prepared/certified Family Physician to be the core of a single specialty group. OB and procedures are optional. Excellent compensation and benefits available. Located in the beautiful Eastern Upper Peninsula of Michigan, Sault Ste. Marie is a mecca of both winter and summer outdoor recreation and offers a superior quality of life. For more information contact: Elisa Abner-Taschwer at 800-635-4608 or forward your CV to: War Memorial Hospital, 500 Osborn Boulevard, Sault Ste. Marie, MI

IOWA - A FAMILY PHYSICIAN'S FAMILY HAVEN

- Bring your family to a safe wholesome area rich with leisure, cultural and educational opportunities. We are in need of BE/BC Family Physicians to join our growing PHO of primary care physicians. Highly competitive salary and compensation package. Practice patient-oriented medicine in a group concerned with your quality of life. Send CV to: Theresa Alberts, Recruiting Specialist, 855 A Avenue NE, Suite 100, Cedar Rapids, IA 52402. Telephone: 319-366-3400.

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Southwest

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BROOKE ARMY MEDICAL CENTER, FORT SAM HOUSTON, TEXAS — Seeking two Family Practice MD's for new Family Care Clinic. Offers competitive benefit package for board certified FP's. Contact: Family Care Clinic, Building 1279, Garden Avenue, Fort Sam Houston, TX 78234. 210-916-7881 (Mrs. Yon) or 210-916-6288 (Maj. Evans) or fax CV to: 210-916-6595 Attn: Maj.

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ATELY — For BC/BE Family Practitioners to staff family practice clinics in a suppy southeast Texas community close to a large metro city and which offers an excellent quality of life and good schools. Extremely competitive first year net income guarantee with the potential for succeeding years exceptional. With these opportunities the hassle of managing an office is gone. Interview, relocation and marketing expense underwritten. Interested applicants please forward CV to: Pat Adams, AMI Park Place Medical Center, PO Box 1648, Port Arthur. TX 77641 or fax to: 409-983-6152.

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For more information, send CV to:

Ms. Ellen Sakai Physician Recruitment Coordinator Straub Clinic & Hospital, Inc. 888 South King Street Honolulu, Hawaii 96813

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ALBUQUERQUE, NEW MEXICO — BE/BC Family Practice Physicians. Numerous opportunities with the region's leading healthcare system. Competitive salary, personalized benefits and potential for incentive compensation. Send CV: Kay Kernaghan, Physician Coordinator, Presbyterian Healthcare Services, PO Box 26666, Albuquerque, NM 87125. Telephone: 800-545-4030, x6330. Fax: 505-260-6393.

PRACTICE/TEACHING POSITION IN SOUTHERN NEW MEXICO — Memorial Medical Center in Las Cruces, NM is seeking family physician faculty to develop a new family practice residency program in collaboration with the University of New Mexico. Position involves direct patient care (preferably with obstetrics), teaching and involvement in primary care research. Board certification required, fellowship training or prior teaching experience preferred. Competitive salary and fringe benefits, university faculty appointment and excellent quality of life. For information contact: Michael Stehney, MD at 505-521-3045 during the day or 505-521-3891 after 6pm MST.



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RESIDENCY PROGRAM ASSOCIATE DIRECTOR — Fully accredited glorious Northern California Residency Program is seeking board certified Family Physician. Physician Educator or fellowship training preferred. Responsibilities include program director support, resident documentation, and curriculum evaluation; 30% clinical work and 30% teaching are required. OB strongly encouraged. Flexibility, enthusiasm, innovation are key characteristics desired in the ideal candidate. UCDavisaffiliated residency program. Contact: Rich McNabb, MD, MPH, Residency Director, Merrithew Memorial Hospital, 2500 Alhambra Avenue, Martinez, CA 94553, 510-370-5117. Equal Opportunity Employer.

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Richard Brunader, M.D.
Director, Family Practice Residency Program
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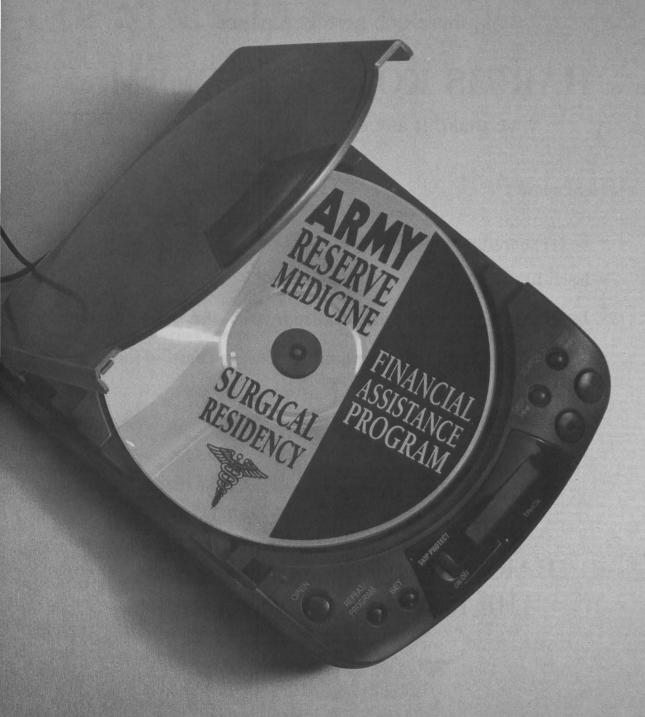
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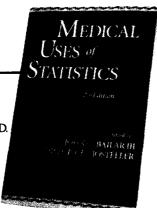
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Acute Abdominal Conditions: The administration of narcotics may obscure the clinical course of adients with nead injuries. Acute Abdominal Conditions: The administration of narcotics may obscure the clinical course of natients with acute abdominal condiobscure the diagnosis or clinical course of patients with acute abdominal condi-tions. PRECAUTIONS: Special Risk Patients: As with any narcotic analgesic agent, Lorcet** 10/650 should be used with caution in elderly or debilitated pathents and those with severe impairment of hepatic or renal function, hypothy-roidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind. Cough Reliex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when Lorce** 10/650 is used postoperatively and in patients with pulmonary disease. Drug Interactions: Patients receiving other narcotic analgesics, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with Lorcet* 10/650 may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibi-tors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticreet or entiret the anticeptessant in rydrocodome. The concurrent use of anti-cholinergics with hydrocodome may produce paralytic ileus. <u>Usage in Pregnancy:</u> <u>Teratogenic Effects: Pregnancy Category C. Hydrocodome has been shown to be</u> teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. <u>Lorcer* 10/650</u> should be used during pregnancy only if the potential benefit justifies the poten-tial risk to the felus. <u>Nonteratogenic Effects</u>: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and lever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal. Chiorpromazine 0.7 to 1 mg/kg q8h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosage decreased as tolerated. Labor and Delivery: As with all narcotics, administration of Lorcet* 10/650 to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used. Nursing Mothers: It is not known whether this drug is excreted in human milk Besuse many drugs are excreted in human milk and Lecause of the potential for serious adverse reactions in nursing infants from Lorcet* 10/650, a decision should be made whether to discontinue mursing or to discontinue the drug, taking into account the importance of the drug to the mother. Pediatric Use: Salety and effectiveness in children have not been established. ADVERSE REACTIONS: The most frequently observed adverse reactions include lightheadedness, dizziness, sedafrequently observed adverse reactions include lightheadedness, dizziness, seda-tion, nausea and vomiting. These effects seem to be more prominent in ambula-tory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: Central Neralleviated if the patient lies down. Other adverse reactions include: Central Ner-vous System: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence, mood changes. Gastrointestinal System: The antiemetic phenothiazines are useful in suppressing the nausea and overniting which may occur (see above): however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of Lorcet® 10/650 may produce constipation. **Genito**-Prolonged administration of Lorcete* 10/550 may produce a given level or analgesia. Prolonged administration of Lorcete* 10/550 may produce constipation. Gentlourinary System: Ureteral spasm. spasm of vesical sphincters and urinary retention have been reported. Respiratory depression: Hydrocodone bitartrate may
produce dose-related respiratory depression by acting directly on the brain stem
respiratory center: Hydrocodone also affects the center that controls respiratory
tythm, and may produce tregular and petiodic breathing. It significant respiratory depression occurs, it may be antagonized by the use of naixone hydrochloride. Apply other supportive measures when indicated. DRUB ABUSE AND DEPENDENCE: Lorcete* 10/650 is subject to the Federal Controlled Substances Act
Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore. Lorcete* 10/650
should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when Lorcete* 10/650 is used for a short time for the
treatment of pain. OVERDOSABE. Actammophen: Signs and Symptoms: in
acute acetaminophen overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal lubular necrosis, hypoplycemic
coma, and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoress and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. Hydrocodone is ginar and Symptoms:
Serious overdose with hydrocodone is characterized by respiratory depression (a
decrease in respiratory rate and/or tidal volume. Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma. skeletal muscle flactions of the control of the con nosis), extreme sommolence progressing to stupor or coma, skeletal muscle flac-cidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related. The usual adult dosage is one tablet every four to six hours as needed for pain. The total 24 hour dose should not exceed 6 tablets. CAUTION: Federal law prohibits dispensing without prescription. A Schedule CIII Controlled Substance. Manufactured by: MIKART, INC. ATLANTA, GA 30318 Manufactured for UAD Laboratories Division of Forest Pharmaceuticals, Inc. St. Louis, MO 63045 Rev. 6/94

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