In 1987, Galveston Manufacturing introduced the Galveston Metacarpal Brace™. After over seven years of clinical use, the brace has proven successful in treating metacarpal shaft fractures. Galveston Manufacturing has continued serving the medical community, bringing you the latest quality fracture management products at affordable prices. So far this year we've introduced three new products to our line; the THUMZ'UP® functional thumb splint, the ORFIZIP® removable casting system and the PLAST-O-FIT® thermoplastic bandage for immobilization.

For ordering information or a product catalog, simply call 1-800-634-3309. These products will be displayed at the AAFP in Boston, booth #1114.
and tumors) was observed. Metoprolol, which has greater negative inotropic effect, is safer in patients with heart failure and has not been established. Caution should therefore be exercised when using PLENOL in patients with heart failure or compromised ventricular function, particularly in combination with a beta blocker.

Elderly Patients or Patients with Impaired Liver Function: Patients over 65 years of age or patients with impaired liver function may have elevated plasma concentrations of felodipine and may therefore respond to lower doses of PLENOL. These patients should have their blood pressure monitored closely during dosage adjustment of PLENOL. Such patients should receive doses 10 mg or above. See CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION sections of complete prescribing information.

Periproctal Edema: Periproctal edema, generally mild and not associated with generalized fluid retention, was the most common adverse event in the clinical trials. The incidence of periproctal edema was both dose-related and dependent. Frequency of periproctal edema ranged from approximately 10 to 20 percent in patients under 50 years of age and 5 to 10 percent in over 50 years of age taking 2.5 mg daily. A dose-related adverse effect generally occurs within 2-3 weeks of the initiation of treatment.

Information for Patients

Patients should be instructed to take PLENOL whole and not to crush or chew the tablets. They should be told that mild gingival hyperplasia (gum swelling) has been reported. Good dental hygiene decreases the incidence of gingival hyperplasia.

NOTE: As with many other drugs, certain advice to patients being treated with PLENOL is warranted. This information is intended to be used in the context of effective patient education. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions

Drug interactions with felodipine are not significant to a clinically meaningful extent. In in vitro and in vivo studies of metoprolol and felodipine coadministered in the cynomolgus monkey, no significant interactions were noted. Hence, the clinician need not concern himself with the possibility of drug interactions between felodipine and metoprolol.

Cimetidine: In healthy subjects pharmacokinetic studies showed an approximately 50 percent increase in the area under the plasma concentration-time curve IAUC) when felodipine was coadministered with cimetidine. The Cmax and Tmax of felodipine were also reduced to a similar extent. This may be due to cimetidine's inhibition of hepatic metabolism of felodipine. Cimetidine may therefore be used in combination with felodipine if an increase in serum felodipine levels is anticipated.

Hypertension: In general, felodipine, like other calcium antagonists, may occasionally precipitate significant hypertension and rare syncope. It may lead to reflex tachycardia which in susceptible individuals may precipitate a further rise in blood pressure and lead to angina. These effects are dose-related and may require discontinuation of therapy.

Heart Failure: Although acute hemodynamic studies in a small number of patients with NYHA Class II or III heart failure treated with felodipine demonstrated a modest decrease in left ventricular filling pressures, similar side effects were observed in healthy volunteers.

Fertility: In animal studies, felodipine did not significantly affect fertility. Based on the animal data, it is expected that felodipine may not impair fertility in humans.

Pregnancy

Category C

Pregnancy Category: The use of felodipine during pregnancy is not recommended. The potential hazard to the fetus, possible digitalis toxicity, and not to exceed the maximum recommended human dose on a mg/m2 basis or in vitro in the human lymphoma transformation assay. In a study in mice where pregnant females were given felodipine, the incidence and severity of tumors (both benign and malignant) was similar for those animals that received felodipine and those that did not. It is known that felodipine increases the serum concentration of felodipine in benign and malignant tumors in mice and other species, and this is possibly secondarily due to the increased tumor cell growth observed in vivo. These tumors were not observed in the two-year carcinogenicity studies in rats fed felodipine at doses of 7.7, 23.1 or 69.3 mg/kg/day (up to 28 times the maximum recommended human dose on a mg/mg basis). Therefore, at the doses employed in the two-year rat studies, these tumors may have been due to an unquantified contribution to a corresponding increase in serum 1umetanin in rodents. The Leydig cell tumor development is presumably secondary to these hormonal effects, and not in itself an oncogenic effect.

In this same rat study a dose-related increase in the incidence of focal squamous cell hyperplasia compared to control was observed in the gastric groove of male and female rats in all dose groups. No other drug-related changes in organ or pathology were observed in the rats or with chronic administration in mice and dogs. The latter

BRIEF SUMMARY

PLENOL (Felodipine) Tablets

EXTENDED-RELEASE TABLETS

INDICATIONS AND USAGE

PLENOL is indicated for the treatment of hypertension. PLENOL may be used alone or concomitantly with other antihypertensive agents.

CONTRAINDICATIONS

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

PRECAUTIONS

General

Hypertension: In a cardiovascular-congestive heart failure study, the reduction in mean arterial blood pressure during felodipine therapy was greater than in healthy volunteers. The patient's blood pressure and heart rate were normal on admission to hospital; he subsequently recovered without significant sequelae.

Overdosage

Inadvertent oral doses of 240 mg and 254 mg in male and female mice, respectively, and 2350 mg in male and female rats, respectively, caused significant lethality. In a suicide attempt, one patient took 150 mg felodipine together with 12 tablets each of chloral hydrate and trivalent barium tablets of nitrampam. The patient's blood pressure and heart rate were normal on admission to hospital; he subsequently recovered without significant sequelae. Vascular toxicity may be caused by excessive peripheral vasodilatation with marked hypotension and possibly bradycardia. If severe hypotension occurs, symptomatic treatment should be instituted. The patient should be supine with the legs elevated. The administration of intravenous fluids may be useful to treat hypotension due to overdosage with cardiac glycosides. In case of accompanying bradycardia, atropine (0.5-1 mg) should be administered intravenously. Sympathomimetic drugs may also be given if the physician feels they are warranted. It has not been established that felodipine can be removed from the circulation by hemodialysis.

DOSAGE AND ADMINISTRATION

The recommended initial dose is 5 mg once a day. Therapy should 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 dosage is 10 mg once a day. That dosing clinical trials showed an increased U.S. pressure response but a large increase in the rate of peripheral edema and other vasodilatory adverse events (see ADVERSE REACTIONS: Modification of dosage). Felodipine treatment is usually not required in patients with renal impairment. PLENOL 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 may have elevated plasma concentrations of felodipine and may therefore respond to lower doses of PLENOL. Since felodipine is extensively metabolized, the recommended dose of PLENOL should be reduced in these patients. PLENOL is a product of Astra/Merk Research Copyright ©1994 by Astra/Merk Group of Merck & Co., Inc. All rights reserved. 725 Chesterbrook Boulevard, Wayne, PA 19087

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MERCK & CO., INC.
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\(^1\) (clinical significance unknown).

With no objective evidence of tolerance or rebound insomnia
In studies of up to 35 consecutive nights at recommended doses.\(^{1,2}\)

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

<table>
<thead>
<tr>
<th></th>
<th>Short-term: ≤10 nights</th>
<th>Long-term: 28 to 35 nights</th>
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<tbody>
<tr>
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<td>dizziness</td>
</tr>
<tr>
<td>dizziness</td>
<td>1%</td>
<td>drugged</td>
</tr>
<tr>
<td>diarrhea</td>
<td>1%</td>
<td>feelings</td>
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Please see references and brief summary of prescribing information on the last page of this advertisement.
**INDICATIONS AND USAGE**

Ambien is used in the treatment of insomnia. Hypnoses should generally be limited to 7 to 10 days duration, and the use of controlled substances should be avoided if they are to be taken for more than 2 to 3 weeks.

**DOSAGE AND ADMINISTRATION**

Ambien should be administered in doses of 5 mg or 10 mg (Zolpudem) at bedtime. Higher doses are typically not needed, and doses greater than 10 mg should not be exceeded. Patients should be cautioned against engaging in activities requiring mental alertness (e.g., driving, operating hazardous machinery) until they are assured of their tolerance to the drug.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

Since sleep disturbances may be a manifestation of a primary psychiatric or other physical and/or psychiatric disorder, discontinuation should be done carefully. The use of controlled substances should be avoided if they are to be taken for more than 2 to 3 weeks. The use of controlled substances should be avoided if they are to be taken for more than 2 to 3 weeks.

**ADVERSE REACTIONS**

**Gastrointestinal System**

Nausea, vomiting, abdominal pain, constipation.

**Respiratory System**

Respiratory depression, pharyngitis.

**Skin and Appendages**

Rash, pruritus.

**Other**

Headache, dizziness, somnolence, dry mouth.

**OVERDOSAGE**

No special management is necessary. In patients without respiratory depression, the use of stimulants should be avoided. In patients with respiratory depression, the use of stimulants should be avoided.

**REFERENCES**


**SEARLE**

Box 5110
Chicago, IL 60606-5110

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