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Jan,-Feb.	Dec. 1, 1992	March-Api	Feb. 1, 1993
MayJune	Apr. 1, 1993	July-Aug.	June 1, 1993
Saat Oct	Aug. 2, 1993	NovDec.	Oct. 1, 1993
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NORTHEAST

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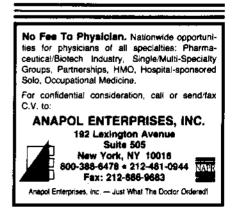
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(Brief Summary, See Package Circular for full prescribing information.)

CONTRAINDICATIONS: SECTRAL is contraindicated in: 1) persistently severe bradycardia, 2) second- and third-degree heart block; 3) overt cardiac failure:

4) cardiogenic shock. (See WARNINGS) WARNINGS: Cardiac Failure: Sympathetic stimulation may be essential for support of circulation in patients with diminished myocardial contractility and inhibition by of circulation in patients with diminished myocardial contractility and inhibition by β -adrenergic receptor blockade may precipitate more severe failure. Although β -blockers should be avoided in overt cardiac failure. SECTRAL can be used cautiously when heart failure is controlled with digitalis and/or diuretics. Digitalis and SECTRAL impair AV conduction. Withdraw SECTRAL if cardiac failure persists. In Patients Without a History of Cardiac Failure: In patients with aortic or mitral valve disease or compromised left ventricular function, continued depression of the myocardium with β -blockers over time may lead to cardiac failure. Digitalize patients at first signs of failure, and/or give a diuretic and observe closely. Withdraw SECTRAL if cardiac failure persists.

cardiac failure persists.

carciac tailure persists. Exacerbation of jachamic Heart Disease Following Abrupt Withdrawai: Abrupt discontinuation of some B-blockers in coronary artery disease patients may exacerbate angina, in some cases. myocardial infarction and death have been reported. Caution such patients against inferruption of therapy without a physician's advice. Even in the absence of over ischemic heart disease, withdraw SECTRAL gradually over a period of about humane. Obsence carefully, and even a patients to minimize physical activity of about two weeks, observe carefully and advise patients to minimize physical activity during this time. (If desired, patients may be transferred directly to comparable doses of an alternative 8-blocker without interruption of 9-blocking therapy.) If exacerbation of applies one many full desired by the second secon angina occurs, restart full-dose anti-anginal therapy immediately and hospitalize Patient until stabilized

Peripheral Veacular Disease: β-antagonists reduce cardiac output and can becipitate/aggravate arterial insufficiency in patients with peripheral or mesenteric vascular disease. Exercise caution and observe such patients closely for progression of arterial obstruction.

or anomal obstruction. Bronchospestic Diseases: Patients with Bronchospestic Disease Should, in General, Not Receive a β -Blocker. Because of its relative β_1 -selectivity, low doses of SECTRAL may be used cautously in such patients who do not respond to, or cannot Nerror and the dose of the second to do the second to do the second to do the Nerror and the dose of the second to do the Nerror and the second to do the second to dotte do the second to do the second to do the second to dot tolerate, alternative treatment. Since β_1 -selectivity is not absolute and is dose-dependent, use lowest possible dose of SECTRAL initially, preferably in divided doses. Make bronchodilator, e.g. theophylline, or a β_2 stimulant, available in advance with instructions for use

Instructions for use. Aneithesis and Mejor Surgery: The necessity/desirability of withdrawing β-blockers prior to major surgery is controversial; the heart's impaired ability to respond to β-adrenergically mediated reflex stimuli may enhance the risk of excessive myocardial depression during general anesthesia. Difficulty in restarting and maintaining the heartbeat also has been reported with beta-blockers. If freatment is continued, take speciel care when using anesthetics that depress the myocardium; use lowest possible SECTRAL dose SECTRAL, like other β-blockers, is a competitive inhibitor of β-receptor agonists, so its effects can be reversed by cautious administration of such agents (e.g., dobutamine or isoproterenol). Symptoms of excessive vacal tone (e.g., arofound bradvcardia, hypotension) may be corrected with excessive vagal lone (e.g., profound bradycardia, hypotension) may be corrected with BIropine.

Diabetes and Hypoglycemia: B-blockers may potentiate insulin-induced hypoglycemia and mask some symptoms such as tachycardia: dizziness and sweating are usually not significantly affected. Warn diabetics of possible masked by post of possible masked. hypoplycemia

Thyrotoxicoela: β -adrenergic blockade may mask some clinical signs (tachycardia) of hyperthyroidism. Abrupt withdrawal of SECTRAL may precipitate a thyroid storm in patients suspected of developing thyrotoxicosis

patients suspected of developing thyrotoxicosis **PRECAUTIONS: Impaired Ranal or Nepatic Function:** While there are no U.S studies: foreign published experience shows that acebutolol has been used successfully in chronic renal insufficiency. Acebutolol is excreted via the G.I. tract, but the active metabolite, diacetolol, is eliminated manly by the kidney. A linear relationship exists between renal clearance of diacetolol and creatinine clearance (Cl_{cf}), reduce daily dose of acebulolol by 50% when Cl_{cf} is less than 50 mL/min and by 75% when it is less than 25 mL/min. Use cautiously in patients with impaired

by Da when this less that 20 internet of databases of the problems in elderly patients in SECTRAL has been used successfully and without problems in elderly patients in U.S. clinical trials without specific dosage adjustment. However, in the elderly, lower maintenance doses may be required because bloavailability of SECTRAL and its metabolite are approximately doubled.

metabolite are approximately doubled. Information for Patients: Warn patients, especially those with evidence of coronary artery disease, against interruption or discontinuation of SECTRAL without physician supervision. Although cardiac failure tarely occurs in properly selected patients, advise patients to consult a physician if signs or symptoms suggestive of impending CHF, or unexplained respiratory symptoms, develop. Warn patients of possible severe hypertensive reactions from concomitant use of readreapric stimulants, e.g., passi deconcestants used in OTC cold medicines and

a-adrenergic stimulants, e.g., nasal decongestants used in OTC cold medicines and nasal drops

nasar grops. **Clinical Laboratory Findinge:** SECTRAL, like other β -blockers has been associated with development of antinuclear antibodies (ANA). In prospective clinical trials, patients receiving SECTRAL had a dose-dependent increase in the development of positive ANA titlers. Symptoms related to this laboratory abnormality were infrequent observed aNA titlers with the under unservice distribution of SECTRAL Symptoms and ANA titers were reversible upon discontinuation of SECTRAL.

Drug Interactions: Catecholamine-depleting drugs may have additive effects when given with β -blockers. Observe patients treated with both agents closely for evidence of marked bradycardia or hypotension which may present as vertigo, syncope/ presyncope, or orthostatic changes in blood pressure without compensatory techycardia. Exaggerated hypertensive responses have been reported from use of β -adrenergic antagonists with α -adrenergic stimulants, including those in OTC cold remedies and vasoconstrictive nasal drops. Nonsteroidal anti-inflammatory drugs may

blunt antihypertensive effects of beta-blockers. Carcinogenesia, Mutagenesia, Impairment of Fertility: Chronic oral toxicity studies in rats and mice, at doses 15 times the maximum recommended (60 kg) human dose, did not indicate carcinogenic potential for SECTRAL. Diacetolol, the major metabolite in man, was without carcinogenic potential in rats at doses up to 1800 mg/kg/d. In man, was without cardinogenic blocking and uses up to take may not support SECTRAL and diacetoiol also had no mutagenic potential in the Ames Test. No significant impact on reproductive performance or fertility was found in rats following SECTRAL or diacetoiol doses of up to 240 or 1000 mg/kg/d, respectively. **Pregnancy:** *Teratogenic Effects:* Pregnancy Category B: No teratogenic effects were seen in rat or rabbit reproduction studies utilizing SECTRAL doses that were, respectively, approximately 31.5 and 6.8 times the maximum recommended human respectively, approximately \$1.5 and 5.5 times the internation recommended number dose. At this dose in the rabbit, sight fatal growth retardation was noted; this was considered to be a result of maternal toxicity (evidenced by reduced food intake, lowered rate of body weight gain, mortality). Diacetolol studies (doses up to 450 mg/kg/d in rabbit and up to 1800 mg/kg/d in ratis) showed no evidence of fetal harm other than a significant elevation in postimplantation isss with 450 mg/kg/d, a level at which long the postimplantation isso with 450 mg/kg/d, a level at order than a significant elevation in postimption who has marked, a tevel at which food consumption and body weight gain were reduced in rabbit dams; there was a nonstatistically significant increase in incidence of bilateral cataract in rat fatuses from dams treated with 1800 mg/kg/d. There are no adequate and well-controlled trials in pregnant women; SECTRAL should be used during pregnancy only if potential benefit justifies risk to the fatus. Noneratogenic Effects: Human studies indicate that acebutolol and diacetolol cross

Homeracogenic Liness, Homan studies indicate interaced under a separation into direction cross the placental. Neonates of mothers who received acebulooid during pregnancy have reduced birth weight, decreased blood pressure, and decreased hear rate. Labor and Delivery: Effect on labor and delivery in pregnant women is unknown. Animal studies have shown no effect of SECTRAL on the usual course of labor and delivery

Nursing Mothers: Acebutolol and diacetolol appear in breast milk (milk: plasma ratio of 7.1 and 12.2, respectively). Use in nursing mothers is not recommended. Pediatric Use: Safety and effectiveness in childran have not been established. ADVERSE REACTIONS: SECTRAL is well tolerated in properly selected patients Most adverse effects have been mild, not required therapy discontinuation, and tended to decrease as treatment duration increases.

The incidence of treatment-related side effects (volunteered and elicited) derived from U.S. controlled clinical trials in patients with hypertension, angine and arrhythma follows. Numbers represent percentage incidence for SECTRAL (N = 1002) versus

follows. Numbers represent percentage incidence for SECTRAL (N =1002) versus placebo (N=314), respectively *Cardiovascular:* Chest pain 2%, 1%; Edema 2%, 1%. *CNS:* Depression 2%, 1%, Dizziness 6%, 2%; Fatigue 11%, 4%; Headache 6%, 4%; Insornia 3%, 1%; Anormal dreams 2%, 1%. *Dermetologic:* Rash 2%, 1%. *Gastrointestinal:* Constipation 4%, 0%, Diarrhea 4%, 1%; Dyspepsia 4%, 1%; Flatulence 3%, 1%, Nausea 4%, 0% *Genitourinary:* Micturiton (frequency) 3%, <1%. *Musculoskielati:* Arthraigia 2%, 2%; Myalgia 2%, 0%. *Respiratory:* Cough 1%, 0%; Dyspnea 4%, 2%, Rhinitis 2%, <1%. *Special Senses:* Abnormal Vision 2%, 0% The following selected (potentially important) side effects were seen in up to 2% of SECTRAL patients:: *Cardiovascular.* hypotension. bradvacrdia. heart failure. *CNS:*

SECTRAL patients: Cardiovascular hypotension, bradycardia, heart failure. CNS: anxiety hypothypoesthesia, impotence. Skin: pruritus. Gastrointestinat: vomitting, abdominal pain. Genitourinary: dysuria, nocturia. Liver and Biliary, small number of reported cases of liver abnormalities (increased SGOT, SGPT, LDH). In some cases, increased bilirubin or alkaline phosphatase, faver, malaise, dark urine, anorexia, nausea, headache, and/or other symptoms have been reported. In some cases, symptoms and signs were confirmed by rechallenge. Abnormalities were reversible upon drug cessation. *Musculoskeletal:* back and joint pain. *Respiratory:* pharyngitis, wheezing. *Special Senses:* conjunctivitis, dry eye, eye pain. *Autoimmune:* extremely rare reports of systemic lupus erythematosis.

Incidence of drug-related adverse effects (volunteered and solicited) based on SECTRAL dose is shown below. (Data from 266 hypertensive patients treated for 3 months on a constant dose)

Body System	400 mg/day (N ≖ 132)	900 mg/day (N ≈ 63)	1200 mg/day (N = 71)
Cardiovascular	5%	2%	1%
Gastrointestinal	3%	3%	7%
Musculoskeletal	2%	3%	4%
Central Nervous System	9%	13%	17%
Respiratory	1%	5%	6%
Skin	1%	2%	1%
Special Senses	2%	2%	6%
Genitourinary	2%	3%	1%

Potential Adverse Effects: Certain adverse effects not listed above have been reported with other β-blocking agents and should be considered as potential adverse effects of SECTRAL

CNS: Reversible mental depression progressing to catatonia, an acute syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Cardiovascular: Intensification of AV block (see CONTRAINDICATIONS). Allergic: Erythematous rash, fever with aching and sore throat, laryngospasm, respiratory distress.

Hematologic: Agranulocytosis, nonthrombocytopenic and thrombocytopenic purpura. Gastrointestinat: Mesenteric arterial thrombosis, ischemic colitis. Miscellaneous: Reversible alopecia, Peyronie's disease. The oculomucocutaneous syndrome associated with practolol has not been reported with SECTRAL

Keep at room temperature, Approximately 25°C (77°F).

3482-5 6/21/89

