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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. Blood pressure without compensatory increase in tachycardia. Exaggerated hypertensive responses have been reported from use of β-adrenergic antagonists with α-adrenergic stimulants, including those in OTC cold remedies. Potentially additive or antagonistic cardiovascular and antihypertensive effects of beta-blockers.

Cardiogenic, Myonecrosis, Impairment of Fertility: Chronic oral toxicity studies in rats and rabbits, at doses 15 times the maximum recommended human dose, did not indicate cardiogenic potential for SECTRAL. Diclofenac, the major metabolite in man, was without cardiogenic potential in rats at doses up to 1800 mg/kg. SECTRAL and diclofenac and their respective metabolites were found to be devoid of significant impact on reproductive performance or fertility was found in rats following SECTRAL or diclofenac with doses of up to 240 or 1000 mg/kg, respectively.

Pregnancy: Teratogenic Effects: Rare, no fetal effects were seen in rat or rabbit reproduction studies utilizing SECTRAL dosages that were, respectively, approximately 31.5 and 6.8 times the maximum recommended human dose. At this dose in the rabbit, slight fetal 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). Diclofenac studies (doses up to 450 mg/kg in rabbits and up to 1900 mg/kg in rats) showed no evidence of fetal harm other than a significant elevation in postimplantation loss with 450 mg/kg, a level at which food consumption and body weight gain were reduced. In dams, there was a nonstatistically significant increase in incidence of bilateral cataract in rat fetuses from dams treated with 1800 mg/kg. 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 fetus.

Nursing Mothers: Acetobucol and diclofenac appear in breast milk (milk, plasma ratio of 71 and 12, respectively) as well tolerated in properly selected patients. Mothers who do not require therapy discontinuation, and prolonged as a decrease in treatment duration increases.

The incidence of treatment-related side effects (volunteered and elicited) derived from U.S. controlled clinical trials in patients with hypertension as shown follows. Numbers represent percentage incidence for SECTRAL (N=1002) versus placebo (N=314), respectively: Cardiac: Chest pain 2%, 1%; Edema 5%, 1%. CNS: Dizziness 6%, 2%; Fatigue 11%, 4%; Headache 6%, 4%; Insomnia 3%, 1%. Abnormal laboratory values: thymus 2%, 1%. Dermatologic: Rash 2%, 1%. Gastrointestinal: Constipation 4%, 0%; Diarrhea 4%, 1%; Dyspepsia 4%, 1%; Flatulence 3%, 1%; Nausea 4%, 0%. Genitourinary: Nystagmus (frequency) 3%, <1%; Myalgia 2%, 0%; Myopathy 4%, 0%. Respiratory: Cough 1%, 0%; Dyspnea 4%, 2%; Rhinitis <1%, 0%; Special Sensations: Abnormal Vision 2%, 0%.

The following selected (potentially important) side effects were seen in up to 2% of SECTRAL patients: Cardiovascular: hypotension, bradycardia; Hypertension: anxiety/fatigue, impotence; Skin: pruritus; Gastrointestinal: vomiting, abdominal pain. Genitourinary: dysuria, nocturia. Liver and Bilir: small number of reports of cases of liver abnormalities (increased SGOT, SGPT, LDH). In some cases, increased bilirubin or alkaline phosphatase, fever, melena, dark urine, anorexia, nausea, headache, and/or other symptoms have been reported. In some cases, symptoms and signs continued and may have been irreversible upon drug cessation. Musculoskeletal back and joint pain. Respiratory: pharyngitis, wheezing. Special Sensations: conjunctivitis, dry eye, eye pain. Autonomic: extremely rare reports of systemic lupus erythematosus.

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.)

<table>
<thead>
<tr>
<th>Body System</th>
<th>400 mg/day</th>
<th>800 mg/day</th>
<th>1200 mg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>5%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3%</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>2%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>1%</td>
<td>3%</td>
<td>17%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>1%</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Skin</td>
<td>1%</td>
<td>2%</td>
<td>6%</td>
</tr>
<tr>
<td>Specific Sensations</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>2%</td>
<td>3%</td>
<td>1%</td>
</tr>
</tbody>
</table>

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: Impaired mental depression progressing to catatonia, an acute syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slighted clouded sensorium, and decreased performance on neuro-psychiatric testing. Cardiovascular: Intensification of AV block (see CONTRAINDICATIONS). Allergic: Erythematous rash, fever with aching and sore throat, laryngospasm, respiratory distress.


Miscellaneous: Reversible alacunia, memory loss, behavioral changes, like hypomnoucatous syndrome associated with pradolin has not been reported with SECTRAL. Keep at room temperature, Approximately 25°C (77°F).

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