Prevent the event

PLATELET ADHESION INHIBITOR

Persantine®

dipyridamole

Tablets of 25, 50 and 75 mg

Prevents thromboembolic events when used in combination with coumarin anticoagulants in cardiac valve replacement

Indicate "Medically necessary"
Protect your choice of medication

Please see brief summary of prescribing information on next page.
Persantine®
(dipyriramol)
Tablets of 25, 50 and 75 mg

Brief Summary of Prescribing Information

CONTRAINDICATIONS
None known.

PRECAUTIONS
General
Persantine® (dipyriramol USP) should be used with caution in patients with hypotension since it can produce peripheral vasodilation.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In a 111 week oral study in mice and in a 128-142 week oral study in rats, Persantine produced no significant carcinogenic effects at doses of 8, 25 and 75 mg/kg (1, 3.1 and 9.4 times the maximum recommended daily human dose). Mutagenicity testing with Persantine was negative. Reproduction studies with Persantine revealed no evidence of impaired fertility in rats at dosages up to 60 times the maximum recommended human dose. A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 155 times the maximum recommended human dose.

Teratogenic Effects
PREGNANCY CATEGORY B
Reproduction studies have been performed in mice and rats at doses up to 125 mg/kg (15.6 times the maximum recommended daily human dose) and rabbits at doses up to 50 mg/kg and have revealed no evidence of harm to the fetus due to Persantine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers
As dipyriramol is excreted in human milk, caution should be exercised when Persantine is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in children below the age of 12 years has not been established.

ADVERSE REACTIONS
Adverse reactions at therapeutic doses are usually minimal and transient. On long-term use of Persantine® (dipyriramol USP) initial side effects usually disappear. The following reactions were reported in two heart valve replacement trials comparing Persantine and warfarin therapy to either warfarin alone or warfarin and placebo:

<table>
<thead>
<tr>
<th>Persantine/ Warfarin</th>
<th>Placebo/ Warfarin</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N = 147)</td>
<td>(N = 170)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>13.6%</td>
</tr>
<tr>
<td>Abdominal distress</td>
<td>6.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
</tr>
<tr>
<td>Rash</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Other reactions from uncontrolled studies include diarrhea, vomiting, flushing and pruritus. In addition, angina pectoris has been reported rarely. On those uncommon occasions when adverse reactions have been persistent or intolerable, they have ceased on withdrawal of the medication.

When Persantine was administered concomitantly with warfarin, bleeding was no greater in frequency or severity than that observed when warfarin was administered alone.

HOW SUPPLIED
Persantine® (dipyriramol USP) is available as round, orange, sugar-coated tablets of 25 mg, 50 mg and 75 mg in the following package sizes:

- 25 and 50 mg Tablets: Bottles of 100 and 1000, unit dose of 100.
- 75 mg Tablets: Bottles of 100 and 500, unit dose of 100.

Consult package insert before prescribing.

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