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Adverse Reactions

Adverse effects associated with the vascular activity of isosorbide mononitrate are common and as expected with all nitrate preparations. They occur mainly in the early stages of treatment. Headache predominates (up to 30%). However, the incidence of headache reduces rapidly as treatment continues. Only 2 to 3% of patients withdrew from clinical trials of isosorbide mononitrate due to this adverse effect.

Hypotension (4%) with symptoms such as dizziness and nausea have been reported. These symptoms generally disappear during long-term treatment.

The following adverse reactions have been reported in studies with isosorbide mononitrate.

Cardiovascular. Hypotension (4 to 5%), tachycardia.

Central nervous system. Headache, vertigo

Gastrointestinal. Poor appetite (2.5%), nausea (1%), vomiting, diarrhoea, heartburn.

Tiredness, sleep disturbances (6%) and gastrointestinal disturbances (6%) have been reported during clinical trials with isosorbide mononitrate sustained release tablets, but at a frequency no greater than for placebo.

Dosage and Administration

1 tablet once daily. The dose may be increased to 2 tablets daily. Both tablets should be taken at the same time.

Twice daily dosing should not be used with Duride.

If headache occurs, the initial dose may be reduced to half a tablet once a day until the headache disappears. Patients with severe renal impairment may require dosage reduction to half a tablet given once daily.

Duride sustained release tablets should be swallowed whole with half a glass of fluid. The tablets should not be crushed or chewed. Half tablet doses may be administered without affecting the sustained release properties of Duride, if care is taken not to crush or chew the tablets.

Overdosage

Symptoms. The most common symptom of overdose is a pulsing headache. More serious symptoms are a fall in blood pressure, cold sweats, excitation, flushing, nausea and vomiting, syncope, tachycardia and vertigo.

Treatment. Induce emesis if possible, then administer activated charcoal. In patients with severe hypotension, place patient in a supine position with the legs raised. Further symptomatic treatment, including intravenous fluid administration, should be given if necessary.

Presentation

Duride isosorbide mononitrate 60 mg sustained release tablet: yellow, oval, marked IM | 60 on one side and scored on both sides; 30's

Poison Schedule

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