

Monate[®]

Tablet

Description

Monate contains Isosorbide Mononitrate which is an organic nitrate. It is a vasodilator, active on both arteries and veins.

Dosage and Administration

Adults: The recommended dosage is from 20 to 120 mg daily in divided doses. The majority of patients will require a dosage in the range of 40 to 60 mg daily in divided doses. The tablets should be taken with fluid and swallowed whole without chewing.

Elderly: There is no evidence to suggest an adjustment of dose. However, caution may be required in elderly patients who are known to be susceptible to the effects of hypotensive medication.

Children: The safety and efficacy of Isosorbide Mononitrate in children has not been established.

Indications

Monate tablets are indicated for prophylaxis of angina pectoris and as an adjunct to treatment of heart failure.

Contraindications

Isosorbide Mononitrate is contraindicated in patients with a known hypersensitivity to Isosorbide Mononitrate or Isosorbide Dinitrate. It is also contraindicated in cases of marked low blood pressure, shock and acute myocardial infarction with low left ventricular filling pressure.

Precautions

Isosorbide Mononitrate tablet is not indicated for the relief of an acute attack when sublingual or buccal Glyceryl Trinitrate tablets or spray should be used. In the case of acute myocardial infarction, Isosorbide Mononitrate tablets should be continued only under strict medical supervision. Since a rebound phenomenon cannot be excluded, therapy with Isosorbide Mononitrate should be terminated gradually rather than stopping abruptly.

Drug Interactions

Orthostatic hypotension may occur with combined use of calcium channel blockers, antihypertensive agents, phenothiazines or tricyclic antidepressants. Use of alcohol with Isosorbide Mononitrate may produce severe hypotension and collapse.

Side Effects

A number of nitrate related adverse effects may occur during treatment including headache and feelings of dizziness. The incidence of such effects is normally highest at the commencement of treatment and tends to decline with time. In highly sensitive patients hypertension may occur, especially after a high dose. Other reactions, including feelings of weakness, nausea or vomiting may occur occasionally. Side effects that have been associated with Isosorbide Dinitrate (e.g., flushing, postural hypotension, dry rash, exfoliative dermatitis) may also occur.

Use in Special Populations

Pregnancy : No data have been reported which would indicate the possibility of adverse effects resulting from the use of organic nitrates in pregnancy. However, safety in pregnancy has not been established.

Lactation : There is no information on excretion of Isosorbide Mononitrate in breast milk. Use in lactation is not recommended unless considered essential by the physician.

Commercial Pack

Monate[®] Tablet : Box containing 100 tablets in 10 x 10's blister strips. Each tablet contains Isosorbide Mononitrate BP 20 mg.