

Isosorbide-5-mononitrate

The active substance of MONOCINQUE retard is isosorbide-5-mononitrate, an active metabolite of isosorbide dinitrate, a drug largely used for treatment of coronary insufficiency. Compared to dinitrate, MONOCINQUE retard offers two advantages: a better bioavailability after oral administration and more prolonged action.

The special formulation of MONOCINQUE retard with a sustained release of the active principle ensures blood levels being therapeutically active during 24 hours with a single daily administration.

This drug is particularly indicated for prolonged treatment of coronary diseases.

**INDICATIONS**

Maintenance therapy of coronary insufficiency, prophylaxis of angina pectoris attacks, treatment of myocardial post-infarction, maintenance therapy of chronic myocardial insufficiency also in combination with cardiotonics and diuretics.

Due to its pharmacological profile, MONOCINQUE retard should not be used to control acute stenocardial episodes.

**CONTRA-INDICATIONS**

Known individual hypersensitivity to isosorbide, both mononitrate and dinitrate. The drug should not be administered in cases of myocardial infarction at acute stage, of acute circulatory failure (shock, vascular collapse) and of severe arterial hypotension.

In case of arterial hypotension, the drug should be administered only upon medical prescription.

**SIDE EFFECTS**

At the prescribed doses, no significant side effects have been reported. As with all nitroderivatives, the following side effects may occur: headache of varying incidence, cutaneous vasodilation with flushing, transient episodes of dizziness and asthenia, orthostatic arterial hypotension, cutaneous manifestations, exfoliative dermatitis. Occasionally, a marked sensitivity to hypotensive effects of nitroderivatives may develop and therefore severe symptoms such as nausea, vomiting, asthenia, restlessness, pallor, sweating and collapse may occur even at therapeutic doses. If one or more of these side effects occur, the patient should refer to the physician.

After the first administration, in patients with labile circulation symptoms of circulatory collapse may arise.

**WARNING**

Use with caution in patients with glaucoma.

In pregnant women the product should be administered only in cases of real need, under the physician's direct supervision.

The drug may act as a physiological antagonist of noradrenaline, acetylcholine, histamine and other substances.

Tolerance to the drug of crossed tolerance with other nitroderivatives may occur.

**DRUG INTERACTIONS AND INCOMPATIBILITY**

The concomitant consumption of alcohol may increase the hypotensive effects of nitroderivatives and reduce the patient's reaction capacity while, for example, driving vehicles or operating machinery.

At high doses, MONOCINQUE retard may potentiate the action of other hypotensive drug being concomitantly administered.

**DOSAGE AND ADMINISTRATION**

Unless otherwise prescribed, dosage is one tablet of MONOCINQUE retard once-a-day in the morning, to be swallowed with a little fluid without chewing.

**PRESENTATION**

Capsules – each capsule contains: isosorbide-5-mononitrate 50 mg.

**Keep out of the reach of children**

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