

MONOCINQUE®

isosorbide-5-mononitrate 40 mg

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

INDICATIONS

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

Owing to its pharmacological properties, this drug should not be used to control acute stenocardial episodes.

CONTRA-INDICATIONS

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

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

SIDE EFFECTS

With 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 vasodilatation with flushing, transient episodes of dizziness and asthenia, orthostatic arterial hypotension, skin rashes, exfoliative dermatitis.

Occasionally, a marked sensitivity to hypotensive effects of nitroderivatives may develop and therefore severe symptoms such as nausea, vomiting, asthenia, restlessness, pallor, perspiration and collapse may occur even with 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. These symptoms, as well as headache from nitrates, may be widely avoided by starting treatment with a half tablet of MONOCINQUE both in the morning and in the evening.

WARNINGS

Use with caution in patients with glaucoma.

During pregnancy and breast-feeding, the drug should be administered only in case of real need, under direct medical supervision. The drug may act as a physiological antagonist to norepinephrine, acetylcholine, histamine and other substances.

Tolerance to this drug and cross-tolerance to other nitroderivatives may occur.

DRUG INTERACTIONS AND INCOMPATIBILITIES

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

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

DOSAGE AND ADMINISTRATION

Unless otherwise prescribed, the dosage is 1 tablet of MONOCINQUE three times daily after meals.

In patients with labile circulation, symptoms of circulatory collapse may arise after the first administration. These symptoms, as well as headache from nitrates, may be widely avoided by starting treatment with a half tablet of MONOCINQUE both in the morning and in the evening. The dosage may be adjusted by the physician according to the patient's condition.

PRESENTATION

30 Tablets package.

Each tablet contains: isosorbide-5-mononitrate 40 mg.

Keep out of the reach of children.

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