

MONOTILDIEM SR 200 mg, SR 300 mg Sanofi-Aventis

Composition

Sustained-release capsules containing microspheres: diltiazem hydrochloride 200 mg, diltiazem hydrochloride 300 mg.

Indications

Preventive treatment of angina pectoris attacks. Arterial hypertension.

Contraindications

Sick sinus syndrome, second and third degree AV block in patients not fitted with a pacemaker. Left ventricular failure with pulmonary stasis. Pregnancy.

Side Effects

Headache and/or hot flushes and/or malaise, edema of the lower limbs, gastro-intestinal disturbances, skin rashes, asthenia, palpitation. Manifestations of vasodilation are dose-dependent and appear to be more frequent in elderly subjects.

Very rarely: symptomatic bradycardia, sino-atrial block, atrio-ventricular block.

A few cases of isolated, moderate and transient elevation of liver transaminases have been observed at the beginning of treatment. A few rare cases of clinical hepatitis have been reported.

Precautions

In case of general anaesthesia, the anaesthetist should be informed that this drug is being taken.

Breast feeding while taking this drug is inadvisable.

Drug Interactions

Associations contraindicated by prudence: Dantrolene, alpha-antagonists, beta-blockers, amiodarone, digoxin, antiarrhythmic drugs, nitrite derivatives, cyclosporin, carbamazepine, theophylline, H₂ histaminergic receptor antagonists.

Dosage and Administration

Angina and Hypertension.

Adults: the usual starting dose is one 200 mg cap-

sule once daily. Doses of 300 mg once a day may be required to provide adequate blood pressure control in certain hypertensive patients.

Elderly Patients: The recommended starting dose is one 200 mg capsule per day.

Risk Patients: In elderly patients and patients with kidney or liver failure, the daily dose must not exceed 200 mg once a day.

Packaging

ca: 200 mg, 300 mg x 28.