Kerlone® 20 mg

betaxolol

Scored film-coated tablets

Please read all of the leaflet carefully before taking this medicine.
- Keep this leaflet you may need to read it again.
- If you have any other questions or doubts, ask your doctor or pharmacist for further information.
- This medicine has been prescribed personally for you. Do not give it to anybody else, even if he/she has identical symptoms since it might cause harm to him/her.

IDENTIFICATION OF THE MEDICINE

Composition

betaxolol hydrochloride ..... 20 mg

Excipients: Lactose, carboxymethylamidon, microcrystalline cellulose, anhydrous colloidal silica, magnesium stearate, hypromellose, macrogol 400, titanium dioxide q.s.f. one tablet.

Pharmaceutical form and presentation

Scored film coated tablet. Box of 28.

Pharmaco-therapeutic class

BETA-BLOCKER/ANTIANGINAL and ANTIHYPERTENSIVE AGENT

Holder

sanofi-aventis france - 1-13, boulevard Romain Rolland - 75014 Paris - France

Manufacturer

Sanofi Winthrop Industrie - 30-36, avenue Gustave Eiffel - 37100 Tours - France

WHEN THIS MEDICINE SHOULD BE USED

This drug is a beta-blocker. It decreases certain effects ("beta" effects) of the sympathetic system of cardiovascular regulation.

This drug has been approved in:
- arterial hypertension
- preventive treatment of episodes of exertional angina.

ATTENTION!

WHEN THIS MEDICINE SHOULD NOT BE USED

This drug must NOT BE USED in the following cases:
- cardiac insufficiency not controlled by treatment,
- bradycardia (heart rate below 45-50 beats per minute),
- cardiac conduction disturbances,
- severe peripheral arterial disorders,
- hypotension,
- known hypersensitivity to betaxolol,
- in certain severe forms of asthma and obstructive bronchopneumopathies,
- in combination with floctafenine (pain medicine) and with sultopride (nervous system medicine).

The use of this medicine is GENERALLY INADVISABLE with amiodarone, bepridil, diltiazem, verapamil (heart medicines) and while breast-feeding.

IF IN DOUBT, IT IS ESSENTIAL THAT YOU CONSULT YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Special warnings

NEVER SUDDENLY STOP TREATMENT WITHOUT THE ADVICE OF YOUR DOCTOR.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Due to the presence of lactose, this medicinal product is contraindicated in the event of congenital galactosaemia, glucose/galactose malabsorption or lactose deficiency syndrome (rare metabolic disorders).

Precautions for use
- You must inform your doctor if you are pregnant or breastfeeding, or if you are suffering from diabetes, renal insufficiency or psoriasis, or if you have a history of allergies.
- If you have to undergo a surgical operation, you must tell the anaesthetist that you are taking this drug.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST.

Drug interactions and other interactions

IN ORDER TO PREVENT POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, particularly floctafenine, sultopride, amiodarone, bepridil, diltiazem and verapamil, YOU SHOULD SYSTEMATICALLY TELL YOUR DOCTOR OR PHARMACIST OF ANY OTHER MEDICATION YOU ARE TAKING.

Pregnancy – Breast-feeding
- Tell your doctor if you are pregnant.
- It is unadvisable to breastfeed during the treatment.

Sportsmen and sportswomen

Sportsmen and sportswomen should note that this product contains an active principle which may give a positive result in tests conducted during anti-doping checks.

List of excipients which must be specified for the risk-free use of this medicine in certain patients
- Lactose.

HOW TO USE THIS MEDICINE

Dosage

The usual dosage is one 20-mg tablet per day taken as a single dose.

IN ALL CASES, YOU SHOULD STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION.

Method and route of administration

Oral use. The tablets must be swallowed whole with a drink, without chewing.

Frequency and time of administration

In all cases, you should strictly comply with your doctor's prescription.

Treatment duration

In all cases, you should strictly comply with your doctor's prescription.

Management in case of overdose

In case of accidental overdosage, do not hesitate to ask your doctor for advice.

Actions to be taken when one or more doses have been omitted

If in doubt, ask your doctor for advice.

UNWANTED AND UNPLEASANT EFFECTS

AS WITH ALL MEDICINES, THIS PRODUCT MAY GIVE RISE TO VARYING DEGREES OF UNPLEASANT EFFECTS IN CERTAIN PERSONS

The most commonly reported:

fatigue, cool extremities, slowed pulse, gastrointestinal disturbances (stomach pain, nausea, vomiting), impotence, insomnia.

Much more infrequent:

conduction disturbances, cardiac insufficiency, drop in blood pressure, respiratory difficulties, hypoglycaemia, Raynaud's phenomenon (painful episodes with bluish/purplish discoloration of the extremities), aggravation of pre-existing intermittent claudication (pain upon walking related to a disease of the arteries of the legs), various cutaneous manifestations, including exacerbation of psoriasis, tingling of the hands and feet, eye dryness, nightmares.

PLEASE INFORM YOUR DOCTOR OR PHARMACIST ABOUT ALL UNWANTED AND UNPLEASANT EFFECTS NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE EXTERNAL PACKAGING.

Special precautions for storage

Do not store above 25°C.

DATE OF LEAFLET REVISION: June 2005