



(Captopril)

scored tablets

Ingredients:

Captopril

Excipients: microcrystalline cellulose, corn starch, lactose, stearic acid.

Composition

Capoten® 25 mg: 25 mg

Capoten® 50 mg: 50 mg
per scored tablet

Pharmaceutical forms

Capoten® 25 mg scored tablets box of 30 tablets

Capoten® 50 mg scored tablets box of 30 tablets

Pharmaco-therapeutic class

INHIBITOR OF THE ANGIOTENSINE CONVERSION ENZYME (C; cardiovascular system)

Company name and address:

BRISTOL-MYERS SQUIBB

3, rue Joseph Monier

BP 325

92506 RUEIL-MALMAISON CEDEX

INDICATIONS FOR USE

This drug is indicated for the treatment of:

- arterial hypertension;
- congestive heart failure;
- myocardial infarction, if the doctor considers that the patient's condition permits it;
- sequelae of myocardial infarction, if the doctor considers that the patient's condition permits it;
- kidney failure in insulin-dependent diabetes (diabetic kidney disease).

WARNING !

This drug should NOT BE USED in the following conditions:

- allergy to this drug or to other drugs of the same class as Capoten (conversion enzyme inhibitor). Such allergic reactions may include one or more of the following symptoms: hot flushes, respiratory disorders, oedema (swelling) of the hands, feet, face, lips, glottis, and/or larynx;
- during pregnancy or breast-feeding (see next section);
- in case of concomitant treatment with certain diuretics, with potassium salts or with lithium, unless otherwise decided by your physician;
- in case of narrowing (stenosis) of both renal arteries or when only one kidney is present, unless otherwise decided by your physician;
- in case of hyperkalaemia (excess potassium), unless otherwise decided by your physician.

IN CASE OF DOUBT, DO NOT FAIL TO CONSULT YOUR DOCTOR OR PHARMACIST.

Special warnings

- Dry cough and/or allergic reaction with facial oedema may occur during treatment.
- This drug may provoke allergic reactions in patients under haemodialysis. Inform your doctor prior to haemodialysis.
- In case of myocardial infarction, this drug must be initiated in a hospital setting under strict medical supervision.

Precautions for use:

THIS DRUG SHOULD BE USED WITH CAUTION IN THE FOLLOWING CASES:

- strict salt-free diet or prolonged diuretic treatment, especially in subjects with renal artery stenosis, congestive heart failure, or cirrhosis of the liver;
- the doctor will adapt the dose in elderly patients as well as in patients suffering from kidney failure, severe heart failure or insulin-dependent diabetes. The doctor should be notified if such conditions are present;
- Capoten may be used in children only if the treatment is initiated in a hospital setting under medical supervision;
- if surgery is to be undertaken, the anaesthetist should be notified that the patient is under treatment with this drug.

KEEP OUT OF THE REACH OF CHILDREN.

IN CASE OF DOUBT, DO NOT FAIL TO CONSULT YOUR DOCTOR OR PHARMACIST.

Interactions with other drugs, and other interactions

TO AVOID INTERACTIONS WITH OTHER DRUGS, YOUR DOCTOR OR PHARMACIST SHOULD SYSTEMATICALLY BE INFORMED OF ANY OTHER ONGOING TREATMENT, especially with lithium, potassium salts or diuretics (drugs which are also prescribed for the treatment of arterial hypertension and heart failure).

Pregnancy, breast-feeding

The treatment must immediately be suspended if pregnancy is diagnosed. Notify your physician in case of pregnancy and/or breast-feeding.

HOW TO USE THIS DRUG

Dosage:

The dosage varies with the type of condition treated. It should also be adapted to the individual patient. The dosage should not be changed without consulting your doctor.

- Arterial hypertension: the recommended dose is usually 50 to 100 mg/day.
 - Congestive heart failure: the initial dose should be low. The recommended dose is usually 50 to 100 mg/day.
 - Myocardial infarction: the initial dose should be low and initiated in a hospital setting. The recommended dose is usually 100 mg/day.
 - Sequelae of myocardial infarction: Capoten should be initiated in a hospital setting. The recommended dose is usually 75 to 150 mg/day taken in 2 or 3 doses.
 - Diabetic kidney disease: the recommended dose is usually 50 to 100 mg/day.
- IN ALL CASES, CAREFULLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Modality and route of administration

Oral route. Swallow the tablet with a glass of water.

Administration frequency and timing

According to your doctor's prescription.

Capoten® may be taken before, during or after meals.

Duration of treatment

This drug must be taken regularly for as long as your doctor prescribed it, even if it is for a very long period of time. Do not discontinue treatment unless advised to do so by your doctor.

Regular medical follow-up is required, especially to monitor arterial blood pressure and laboratory test results.

What to do in case of overdose

The most likely result of an overdose is a drop in blood pressure.

If major hypotension is noted, the patient should lie down with raised legs.

It is recommended that you inform your doctor immediately.

What to do in case one or more doses have been missed - Inform your doctor.

UNDESIRE AND UNPLEASANT SIDE EFFECTS

AS WITH ANY DRUG, MORE OR LESS UNPLEASANT SIDE EFFECTS MAY OCCUR SUCH AS:

- Headache, tiredness, vertigo, malaise, low blood pressure, skin rash, itching, nausea, loss of appetite, gastrointestinal pain, taste changes, dry cough and various abnormalities in the laboratory test results.

- Stop taking Capoten® in the following cases and immediately contact your doctor: swelling of the face, lips, tongue and/or larynx which entail difficulties in breathing or swallowing.

INFORM YOUR DOCTOR OR PHARMACIST OF ANY UNPLEASANT SIDE EFFECT THAT HAS NOT BEEN MENTIONED IN THIS LEAFLET.

STORAGE

Use before the date of expiry indicated on the box.

RELEASE CONDITIONS

THIS DRUG IS REGISTERED IN LIST I.

DATE OF REVISION OF THIS LEAFLET: February 1997.

THIS IS A MEDICAMENT

- . Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- . Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- . The doctor and the pharmacist are experts in medicine, its benefits and risks.
- . Do not by yourself interrupt the period of treatment prescribed for you.
- . Do not repeat the same prescription without consulting your doctor.

Keep Medicament out of reach of children

Council of Arab
Health Ministers
Union of Arab Pharmacists