PATIENT INFORMATION LEAFLET

Scheduling status

S3

CRAVEDON 6,25 mg tablet

CRAVEDON 12,5 mg tablet

CRAVEDON 25 mg tablet

Carvedilol.

Contains sugar:

CRAVEDON 6,25 mg tablets – 40,73 mg lactose monohydrate per tablet

CRAVEDON 12,5 mg tablets – 81,46 mg lactose monohydrate per tablet

CRAVEDON 25 mg tablets – 162,92 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking CRAVEDON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care professional.
- CRAVEDON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CRAVEDON is and what it is used for

The active substance in CRAVEDON tablets is carvedilol. Each tablet contains either 6,25 mg; 12,5 mg or 25 mg carvedilol.

Carvedilol belongs to a group of medicines called beta-blockers that work by relaxing and widening the blood vessels. This makes it easier for your heart to pump blood around the body and reduces blood pressure and strain on your heart.

Carvedilol is used

- for the treatment of high blood pressure (hypertension)
- for the treatment of heart failure
- for the treatment of heart failure following a recent heart attack

2. What you need to know before you take CRAVEDON

Do not take CRAVEDON

- if you are allergic (hypersensitive) to carvedilol or any of the other ingredients in CRAVEDON listed in section 6
- if you have problems with your heart (for example “heart block”, slow or uneven heart beat)
- if you have low blood pressure
- if you have ever had wheezing due to asthma or other lung diseases
- if you have problems with your liver
- if you have severe fluid retention (swelling of your ankles and feet)

CRAVEDON is not suitable for children.

Do not take CRAVEDON if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking CRAVEDON.

Warnings and precautions

Take special care with CRAVEDON if

- you have a problem with acid levels in your blood (metabolic acidosis)
- you have a growth on one of your adrenal glands (phaeochromocytoma)
- you have diabetes (high blood sugar)
- you have ever had problems with your thyroid
- you have problems with your kidneys
- you have ever had a serious allergic reaction (for example, sudden swelling causing difficulty breathing or swallowing, swelling of the hands, feet and ankles or a severe rash)
- you wear contact lenses
- you have problems with your blood vessels (peripheral vascular disease) or with the blood circulation in your fingers and toes (Raynaud's phenomenon)
- you are going to have an operation tell your doctor that you are taking CRAVEDON, as some anaesthetics can lower your blood pressure
- you have had an allergy and are having treatment to desensitise you
- you have a skin disorder called psoriasis, after taking beta-blocker medicines
- you have a type of angina called "Prinzmetal's variant angina"

Important information about some of the ingredients of CRAVEDON

CRAVEDON contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking CRAVEDON.

Other medicines and CRAVEDON

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- other medicines for your heart or your blood pressure, including water tablets (diuretics), calcium channel blockers (e.g. diltiazem or verapamil), digoxin, and amiodarone

- catecholamine-depleting agents (e.g. reserpine and monoamine oxidase inhibitors (MAOIs)
- fluoxetine and paroxetine (used to treat depression)
- medicines for diabetes, such as insulin or metformin
- rifampicin (used to treat infections)
- guanethidine or bethanidine
- phenothiazines (e.g. chlorpromazine)
- ciclosporin (used after an organ transplant)
- medicines for when your heart does not beat smoothly (e.g. disopyramide, quinidine, procainamide, lignocaine, phenytoin)
- clonidine (used to treat high blood pressure, migraine and flushing in the menopause)
- isoprenaline (used to treat asthma)
- cimetidine (used to treat indigestion, heartburn and stomach ulcers)
- non-steroidal anti-inflammatory drugs (NSAIDs, including aspirin)
- beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other chest conditions (e.g. salbutamol and terbutaline sulphate))
- *operations*: If you are going to have an operation, tell your doctor that you are taking CRAVEDON. This is because some anaesthetics can lower your blood pressure, and it may become too low.

Pregnancy and breastfeeding

There is no adequate clinical experience with CRAVEDON in pregnant women. You should not use CRAVEDON if you are pregnant, as it may harm your unborn baby.

CRAVEDON and/or its metabolites are excreted in breast milk; and therefore you should not take CRAVEDON whilst breastfeeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking CRAVEDON.

Driving and using machines

You may feel dizzy while taking CRAVEDON. This is more likely when you start treatment, or if your treatment has changed, and when you drink alcohol. If this happens to you, do not drive or use any tools or machines. Talk to your doctor if you notice any other problems that might affect driving, using tools or machines while you are taking CRAVEDON.

3. How to take CRAVEDON

Do not share medicines prescribed for you with any other person.

Always take CRAVEDON exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Treatment with CRAVEDON is long-term therapy and should not be stopped abruptly but reduced gradually at weekly intervals.

Swallow the tablets with a glass of water.

High blood pressure

- The usual starting dose is 12,5 mg once a day for two days. After two days the dose is usually 25 mg once a day.
- If you are elderly, you may not need any more than 12,5 mg a day.

Heart failure

- When used for heart failure, treatment with CRAVEDON should be started by a specialist doctor.
- You should take your tablets at the same time as eating some food.
- The usual starting dose is 3,125 mg twice a day for two weeks.
- Your doctor will then increase the dose slowly, over several weeks, up to 25 mg twice a day.
- If you weigh more than 85 kg the dose may be increased to 50 mg twice a day.

If you have stopped taking CRAVEDON for more than two weeks you should talk to your doctor. He will need you to go back to the starting dose again.

Heart failure following a recent heart attack

- When used for heart failure following a recent heart attack, treatment with CRAVEDON should be started by a specialist doctor.
- The usual starting dose is 6,25 mg.
- If you tolerated the first dose, your doctor will then increase the dose to 6,25 mg twice a day and maintain for it 3 - 10 days.
- Your doctor may then increase your dose to 12,5 mg twice a day and then to a maximum of 25 mg twice a day.

Your doctor will decide which dose is best for you and monitor you carefully each time the dose is increased or changed.

If you have the impression that the effect of CRAVEDON is too strong or too weak, tell your doctor or pharmacist.

If you take more CRAVEDON than you should

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

The following effects may happen if you have taken more tablets than you should: a slow heart-beat, feeling dizzy or light headed, becoming breathless, wheezy or extremely tired.

If you forget to take CRAVEDON

If you have missed a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking CRAVEDON

Do not stop taking CRAVEDON without talking to your doctor. He may want you to stop taking CRAVEDON slowly over one to two weeks.

4. Possible side effects

CRAVEDON can have side effects.

Not all side effects reported for **CRAVEDON** are included in this leaflet. Should your general health worsen while taking **CRAVEDON**, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your doctor immediately if you get any of the following side effects:

Severe allergic reactions: signs may include sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.

Chest pains accompanied by shortness of breath, sweating and feeling sick.

Passing water (urinating) less often with swelling of legs, indicating problems with your kidneys.

Very low blood sugar (hypoglycaemia) which might cause seizures or unconsciousness.

Skin reactions - Infrequently, severe skin conditions (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur. Redness, often associated with blisters may appear on the skin or mucous membranes, such as the inside of the mouth, the genital areas or the eyelids. These can appear initially as circular patches often with central blisters, which may progress to widespread peeling of the skin and can be life threatening. These serious skin reactions are often preceded by headache, fever and body aches (flu-like symptoms).

Frequent side effects

- feeling dizzy
- headache
- feeling weak and tired

- low blood pressure. The signs include feeling dizzy or light-headed
- infections of the airway (bronchitis), lung (pneumonia), nose and throat (upper respiratory tract). The signs include wheezing, shortness of breath, chest tightness and sore throat
- infections of the urinary tract which can cause problems in passing water
- low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, a fluttering sensation in your heart (palpitations) and being short of breath
- increase in weight
- increase in cholesterol levels (shown by a blood test)
- loss of control of blood sugar in people with diabetes
- feeling depressed
- problems with your sight, sore or dry eyes due to fewer tears being made
- a slow heart-beat
- feeling dizzy or light-headed after standing up
- fluid retention. The signs include: overall swelling of your body, swelling of parts of your body for example your hands, feet, ankles and legs and shortness of breath
- problems with blood flow to your arms and legs. The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your leg which gets worse when you walk
- breathing problems
- feeling sick or being sick
- diarrhoea
- stomach pain/indigestion
- pain, possibly in your hands and feet
- problems with your kidneys, including changes to how often you pass urine
- disturbed sleep
- fainting
- tingling or numbness of your hands or feet

- problems with your skin, including skin rashes which may cover a lot of your body, a lumpy rash (hives), feeling itchy and dry skin patches
- increased sweating
- hair loss
- being unable to get an erection (erectile dysfunction)
- constipation
- feeling dizzy, having a headache and feeling weak and tired are usually mild and more likely to happen at the beginning of your treatment
- problems with your heart. The signs include heart attack, heart failure - symptoms include shortness of breath, frequent coughing, especially when lying down, swollen feet, ankles, and legs, abdominal swelling and pain, fatigue, dizziness or fainting, chest pains, tiredness, shortness of breath and swelling of your arms and legs

Less frequent side effects

- low numbers of platelets in your blood. The signs include bruising easily and nose bleeds
- a stuffy nose, wheezing and flu-like symptoms
- a dry mouth
- low numbers of all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs
- allergic (hypersensitivity) reactions. The signs may include difficulty breathing or swallowing caused by sudden swelling of the throat, or face or swelling of your hands, feet and ankles
- kidney problems which show up in a blood test

Other side effects that can happen while you are on CRAVEDON therapy:

- Some women may have difficulty with bladder control when they pass water (urinary incontinence)

- Hair loss (alopecia)
- Loss of control of blood sugar in people with diabetes, including aggravation of diabetic symptoms and a mild form of diabetes in which there are no overt symptoms but there are abnormal responses to some test procedures

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CRAVEDON**.

5. How to store CRAVEDON

Store all medicines out of reach of children.

Store at or below 25°C, in the original package. Keep blisters in the carton until required for use.

Do not store in a bathroom.

Do not use **CRAVEDON** after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CRAVEDON contains

The active substance is carvedilol. Each film-coated tablet contains 6,25 mg; 12,5 mg or 25 mg carvedilol.

The other ingredients are microcrystalline cellulose, pregelatinised maize starch, lactose monohydrate, copovidone, glycerol dibehenate, colloidal anhydrous silica, magnesium stearate.

What CRAVEDON looks like and contents of the pack

CRAVEDON 6,25 mg are white, round shaped, biconvex tablets, with uniform appearance and intact edges.

CRAVEDON 12,5 mg are white, round shaped, biconvex tablets, with uniform appearance and intact edges.

CRAVEDON 25 mg are white, round shaped, biconvex tablets, with uniform appearance and intact edges.

The film-coated tablets are packed in PVC / Aluminium foil blisters strips. The blister strips are packed in cartons containing 30 tablets.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7800

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CRAVEDON 12,5 mg tablets: 48/7.1.3/0677

CRAVEDON 25 mg tablets: 48/7.1.3/0678

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/