

## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only.

### **CARVEDEXXON TABLETS 6.25, 12.5 mg**

**Active ingredient:** each tablet contains Carvedilol at dose of 6.25 and 12.5 mg respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

#### **1. What is the medicine intended for?**

**Carvedexxon** is used for the treatment of congestive heart failure.

**Therapeutic group:** Alpha 1 and beta receptor blockers.

#### **2. Before using the medicine**

##### **Do not use the medicine if you:**

- Are hypersensitive (allergic) to the active ingredient (carvedilol), or to any of the other ingredients this medicine contains (see section 6).
- Have ever had wheezing or asthma.
- Have severe heart failure (swelling of your hands, ankles and feet) which is being treated by medicines given into one of your veins (intravenously).
- Have problems with your liver.
- Have problems with your heart (for example: 'heart block' or slow heartbeat). **Carvedexxon** is not suitable for some people with certain types of heart problems.
- Have very low blood pressure.

If any of the above applies to you, do not take this medicine. If you are not sure, talk to the doctor or pharmacist before taking this medicine.

#### **Special warnings regarding the use of the medicine**

- **Before the treatment with Carvedexxon, tell the doctor if you:**
  - Have problems with your lungs.
  - Have problems with your kidneys.
  - Have diabetes (high blood sugar).
  - Wear contact lenses.
  - Have problems with your blood vessels (peripheral vascular disease).
  - Have ever had problems with your thyroid.
  - 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).
  - Have an allergy and are having treatment to desensitise you (to reduce sensitivity to a known allergen).
  - Have problems with the blood circulation to your fingers and toes ('Raynaud's phenomenon').
  - Have ever had a skin disorder called 'psoriasis' after taking beta-blocker medicines.
  - Have a type of angina (chest pain) called 'Prinzmetal's variant angina'.
  - Have a growth on one of your adrenal glands ('phaeochromocytoma').

If any of the above applies to you or if you are not sure, talk to the doctor or pharmacist before taking the medicine.

#### **Children and adolescents**

The medicine is not suitable for children and adolescents under the age of 18 years.

## Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Carvedexxon may affect the way some medicines work. Also some other medicines can affect the way Carvedexxon works.

Especially, Tell the doctor or pharmacist if you are taking:

- Medicines for reducing your blood pressure and for the heart, such as diuretics, ‘calcium channel blockers’ (for example, diltiazem or verapamil), medicines to control an irregular heartbeat (for example, digoxin, amiodarone).
- Catecholamine-depleting agents, for example: reserpine and Monoamine oxidase inhibitors (MAOIs), such as isocarboxazid and phenelzine (used to treat depression).
- Fluoxetine and paroxetine (used to treat depression).
- Medicines for diabetes such as insulin or metformin.
- Clonidine (used to treat high blood pressure, migraine and flushing in the menopause).
- Rifampicin (used to treat infections).
- Ciclosporin or tacrolimus (used to suppress the immune system after an organ transplantation).
- Non-steroidal anti-inflammatory drugs (NSAIDs, for example aspirin, indomethacin and ibuprofen).
- Beta-agonist bronchodilators (used to treat chest tightness and wheezing due to asthma or other lung conditions, for example salbutamol and terbutaline sulphate).

## Use of the medicine and food

Take this medicine with a meal.

Avoid taking this medicine in close proximity to consuming grapefruit or grapefruit juice.

Grapefruit or grapefruit juice can lead to an increase of the active ingredient (carvedilol) in the blood and cause unpredictable adverse effects.

## Use of the medicine and alcohol consumption

Do not drink alcohol while taking this medicine. It could cause your blood pressure to fall too low and increase the risk of you getting side effects.

## Operations

If you are going to have an operation, tell the doctor that you are taking Carvedexxon. Some anaesthetics can lower your blood pressure, and it may become too low.

## Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Taking Carvedexxon when you are pregnant could harm your baby. Do not take Carvedexxon if you are pregnant, or might be pregnant, unless the doctor tells you to. The doctor will discuss with you whether you should take Carvedexxon during the pregnancy.

Do not breast-feed during treatment with Carvedexxon.

## Driving and using machines

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

## Important information about some of the ingredients of the medicine

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

## 3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The usual starting dose is 3.125 mg (half a 6.25 mg tablet) twice a day for two weeks. The doctor will then increase the dose gradually, over several weeks, up to a maximal dose of 25 mg twice a day. If you weigh more than 85 kg, the dose may be increased up to 50 mg twice a day.

If you stop taking **Carvedexxon** for more than two weeks you should talk to your doctor. He may instruct you to go back to the starting dose again (see section “If you stop taking the medicine“).

Elderly:

The usual maximum dose is 50 mg each day, in divided doses.

**Do not exceed the recommended dose.**

Swallow the tablets with some water, with a meal at regular intervals.

The tablets can be halved. There is no information regarding crushing and chewing.

This medicine is not suitable for children under the age of 18 years.

**If you have accidentally taken a higher dosage**, the following effects may occur: a slow heartbeat, sinus arrest (your heartbeat becomes very slow or stops), dizziness, becoming breathless, wheezy or extremely tired.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine** at the designated time, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose. Do not take a double dose!

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

**If you stop taking the medicine**

Do not stop taking this medicine without talking to your doctor. The treatment should be discontinued gradually over a period of 1-2 weeks.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

#### **4. Side effects**

Like any medicine, the use of **Carvedexxon** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**With the occurrence of any the following serious side effects, refer to your doctor or to the hospital emergency room immediately:**

- **Severe allergic reaction** (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 nausea.
- **Sinus arrest** - signs include your heartbeat becoming very slow or stopping. You may feel dizzy, unusually tired and short of breath. This may occur especially in people over 65 years old or in people with other heartbeat problems.
- **Passing urine less often** with swelling of legs, which might indicate on problems with your kidneys.
- **Very low blood sugar (hypoglycaemia)**, which might cause seizures or unconsciousness.
- Severe **skin conditions** (erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis) can occur very rarely. Redness, often associated with blisters 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).

**Other side effects:**

**Very common side effects (effects that occur in more than 1 in 10 users):**

- Feeling dizzy, headache, feeling weak and tired - usually mild and more likely to happen at the

- beginning of your treatment.
- Problems with your heart (the signs include chest pains, tiredness, shortness of breath and swelling of your arms and legs).
- Low blood pressure, the signs include feeling dizzy.

**Common side effects (effects that occur in 1-10 out of 100 users):**

- Infections of the airway (bronchitis), lungs (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 urine).
- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, a fluttering sensation in your heart (palpitations) and shortness 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 heartbeat.
- Feeling dizzy or light-headed after standing up.
- Fluid retention (The signs include: overall swelling of your body or swelling of parts of your body for example your hands, feet, ankles and legs and an increase in blood volume in your body).
- Problems with blood circulation in your arms and legs (The signs include cold hands and feet, whiteness, tingling and pain in your fingers and a pain in your legs that gets worse when you walk).
- Breathing problems.
- Nausea, vomiting, diarrhea, stomach pain, indigestion.
- Pain, possibly in your hands and feet.

**Uncommon side effects (effects that occur in 1-10 out of 1,000 users):**

- 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).
- Hair loss.
- Being unable to get an erection (erectile dysfunction).
- Constipation.

**Rare side effects (effects that occur in 1-10 out of 10,000 users):**

- Low numbers of platelets in your blood, signs include: bruising easily and nose bleeds.
- A stuffy nose, wheezing and flu-like symptoms.
- A dry mouth.

**Very rare side effects (effects that occur in less than 1 in 10,000 users):**

- Low numbers of all types of white blood cells (the signs include: infections of the mouth, gums, throat and lungs).
- Allergic (hypersensitivity) reaction. 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).
- Some women may have difficulty with bladder control (urinary incontinence). This normally will get better when treatment is stopped.

**Side effects with unknown frequency (effects for which a frequency has not yet been determined):**

- This medicine can cause development of the signs of diabetes in people who have a form of diabetes called 'latent diabetes'.
- There have been some reports of hallucinations in patients taking this medicine.
- You may sweat excessively.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link " דיווח על תופעות לוואי עקב טיפול " found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in a dry and dark place, at a temperature below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Additional information**

In addition to the active ingredient, the medicine also contains:  
Microcrystalline cellulose, povidone, sodium starch glycolate (type A), magnesium stearate, silica colloidal anhydrous.

### **What the medicine looks like and what the package contains:**

White to off white, round, biconvex tablets, scored on one side.

Approved package sizes: 10, 30 tablets. Not all package sizes may be marketed.

Revised in November 2022 according to MOH guidelines.

### **Drug registration numbers at the national drug registry of the Ministry of Health:**

**Carvedexxon 6.25:** 127-19-30614-00

**Carvedexxon 12.5:** 127-20-30615-00

### **Manufacturer and registration holder:**

Dexcel Ltd.

1 Dexcel St., Or Akiva 3060000, Israel