

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

Carvedexxon Tablets 6.25, 12.5 mg

Carvedexxon 6.25, Tablets: Each tablet contains 6.25 mg of Carvedilol.

Carvedexxon 12.5, Tablets: Each tablet contains 12.5 mg of Carvedilol.

For full list of excipients – please see section 6 "Additional information".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

1. What is the medicine used for?

For the treatment of congestive heart failure.

Therapeutic group: Alpha 1 and beta receptor blockers.

2. Before you take the medicine Do not use the medicine if:

- You are allergic (hypersensitive) to carvedilol or any of the other ingredients of this medicine (listed in Section 6).
- You have ever had wheezing due to asthma.
- You have severe heart failure (swelling of your hands, ankles and feet) which is being treated by medicines given into one of your veins (intravenously).
- You have problems with your liver.
- You have problems with your heart (for example 'heart block' or slow heart beat). **Carvedexxon** Tablets are not suitable for some people with certain types of heart problem.
- You have very low blood pressure.

Do not take **Carvedexxon** Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **Carvedexxon** Tablets.

Special warnings regarding the use of this medicine

- **Before treatment with Carvedexxon Tablets tell your doctor if:**
 - You have problems with your lungs.
 - You have problems with your kidneys.
 - You have diabetes (high blood sugar).
 - You wear contact lenses.
 - You have problems with your blood vessels (peripheral vascular disease).
 - You have ever had problems with your thyroid.
 - 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 have an allergy and are having treatment to desensitise you (reduce sensitivity to a known allergen).
 - You have problems with the blood circulation in your fingers and toes ('Raynaud's phenomenon').
 - You have had a skin disorder called 'psoriasis', after taking beta-blocker medicines.
 - You have a type of angina called 'Prinzmetal's variant angina'.
 - You have a growth on one of your adrenal glands ('pheochromocytoma').
 - You are sensitive to any type of food or medicine.
- If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take **Carvedexxon** Tablets.
- If you are about to undergo surgery, inform your doctor that you are taking **Carvedexxon** Tablets. This is because some anesthetics can lower your blood pressure and it may become too low.

If you are taking or if you have recently taken any other medicines, including non-prescription drugs and nutrition supplements, please tell your doctor or pharmacist. This because Carvedexxon can affect the way some other medicines work. Also some other medicines can affect the way Carvedexxon works.

Especially if you are taking:

- Other medicines for reducing your heart or blood pressure, including

water tablets (diuretics), 'calcium channel blockers' (for example, diltiazem or verapamil), medicines to control an irregular heartbeat (for example, digoxin and amiodarone).

- Catecholamine-depleting agents, for example, reserpine and Monoamine oxidase inhibitors (MAOIs), such as isocarboxide 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 (suppress the immune system after organ transplants).
- 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 diseases (for example, salbutamol and terbutaline sulphate)).

Use of Carvedexxon with food

Take this medicine with a meal.

Use of Carvedexxon and alcohol consumption

You may feel dizzy while taking **Carvedexxon** Tablets, especially when combined with alcohol.

Pregnancy and breast-feeding

Do not take **Carvedexxon** Tablets if you are pregnant, trying to get pregnant or breast-feeding, unless your doctor has told you to.

Driving and use of machinery

You may feel dizzy while taking **Carvedexxon** Tablets. This is more likely when you start treatment or if your treatment is changed. 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 **Carvedexxon** Tablets.

3. How to use this medicine

Always take **Carvedexxon** Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Dosage and administration will be determined by the physician only.

The usual starting dose is 3.125 mg tablet twice a day for two weeks. The doctor will then increase the dose gradually, over several weeks, up to 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 have stopped taking **Carvedexxon** Tablets for more than two weeks you should talk to your doctor. He may instruct you to go back to the starting dose again.

Elderly: The usual maximum dose is 50 mg each day, taken in small amounts (divided doses).

Do not exceed the recommended dose. Swallow the tablets with a small amount of water, with the meal at regular intervals. Do not crush the tablets, can be halved. There is no information about chewing. This medicine is not suitable for children under the age of 18 years.

If you take more Carvedexxon Tablets than you should, signs of an overdose may include: a slow heart beat, dizziness, becoming breathless, wheezy or extremely tired.

If you have taken an overdose or if a child accidentally swallowed the medicine, contact a doctor immediately or go to a hospital emergency room straight away. Take the medicine pack with you.

If you forget to take a dose at the required time, 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! Continue with the treatment as recommended by your doctor. Even if there is improvement in your health, do not stop this treatment without consulting your doctor.

If you stop taking Carvedexxon Tablets, the treatment should be discontinued gradually over a period of 1-2 weeks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, using **Carvedexxon** Tablets can cause side effects, in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

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 nausea.
- Passing urine less often with swelling of legs, indicating 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 very rarely occur. The symptoms can include: 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).

Additional side effects:

Very common (effects that appear in more than 1 user out of 10 people):

- Feeling dizzy, headache, feeling weak and tired.

- 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 or light-headed.

Feeling dizzy, having a headache and feeling weak and tired are usually mild and more likely to happen at the beginning of your treatment.

Common (effects that appear in 1-10 users out of 100 people):

- 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 an increase in how much blood you have 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 leg which gets worse when you walk.
- Breathing problems.
- Feeling sick or being sick, vomiting, diarrhoea, stomach pain/indigestion.
- Pain, possibly in your hands and feet.
- Problems with your kidneys, including changes to how often you pass urine.
- Fainting.

Uncommon (effects that appear in 1-10 users out of 1,000 people):

- Disturbed sleep.
- 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.

Rare (effects that appear in 1-10 users out of 10,000 people):

- 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.

Very rare (effects that appear in less than 1 user out of 10,000 people):

- 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.
- Some women may have difficulty with bladder control when they pass water (urinary incontinence). This normally will get better when treatment is stopped.

Carvedexxon Tablets can also cause development of the signs of diabetes in people who have a very mild form of diabetes called 'latent diabetes'.

If you experience side effects or if one of the side effects worsens or if you suffer from any side effect not listed in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link [דיווח על תופעות לוואי עקב טיפול](#) "דיווח על תופעות לוואי עקב טיפול", that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via

the following link: <http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.gov.il>

5. How to store the Medicine

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor. Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Do not store at a temperature above 25°C. Store in a dry and dark place. Store in the original package.

6. Additional Information

In addition to the active ingredient, this medicine also contains:

Microcrystalline Cellulose, Povidone, Sodium starch glycolate (type A), Magnesium stearate, Silica colloidal anhydrous.

What the medicine looks like and contents of the pack:

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

Approved pack sizes: 7, 10, 14, 28, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health in: 03/2017.

Drug registration numbers at the national medicines registry of the Ministry of Health:

Carvedexxon 6.25: 127-19-30614-00

Carvedexxon 12.5: 127-20-30615-00

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Manufacturer and registration holder: **Dexcel® Ltd.**

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