PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Carvedilol Teva 6.25 mg

Tablets

Each tablet contains:
Carvedilol 6.25 mg

Carvedilol Teva 12.5 mg

Tablets

Each tablet contains:
Carvedilol 12.5 mg

For information on the inactive and allergenic ingredients, see section 6 – "Further information" and section 2 – "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Carvedilol Teva is intended 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 sensitive (allergic) to the active ingredient (carvedilol) or any of the additional ingredients contained in the medicine (see section 6).
- You are suffering, or have suffered in the past, from wheezing due to asthma.
- You are suffering from severe heart failure (swelling of the hands, ankles or feet), that is being treated by intravenously administered medicines.
- You are suffering from liver problems.
- You are suffering from heart problems (e.g., heart block or slow pulse). Carvedilol Teva is not suitable for treatment of some patients with certain heart problems.
- You are suffering from severe hypotension.

If you are suffering from any of the aforementioned conditions, do not take the medicine. If you are uncertain, consult the doctor or pharmacist before taking the medicine.

Special warnings regarding use of the medicine

Before treatment with Carvedilol Teva, tell the doctor if:
- You have problems with your lungs.
- You have kidney problems.
- You have diabetes (high blood sugar levels).
- You wear contact lenses.
- You have blood vessel problems (peripheral vascular disease).
- You are suffering, or have suffered in the past, from thyroid problems.
- You are suffering, or have suffered in the past, from a severe allergic reaction (e.g., sudden swelling causing breathing or swallowing difficulties, swelling of the hands, feet and ankles, or severe rash).
- You have an allergy and are undergoing desensitization therapy (to reduce the sensitivity to a known allergen).
- You are suffering from disturbances in the blood circulation to the fingers and toes (Raynaud's syndrome).
- You are suffering, or have suffered in the past, from a skin problem called psoriasis, due to use of beta receptor blockers.
- You are suffering from Prinzmetal's angina (chest pain).
- You are suffering from a tumor on one of the adrenal glands (pheochromocytoma).
- You are sensitive to any food or medicine.

If one or more of these conditions apply to you, or if you are uncertain, consult the doctor or pharmacist before taking the medicine.

If you are due to undergo surgery, inform the doctor that you are taking Carvedilol Teva. Certain anesthetics may lower your blood pressure and it may be too low.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.

Carvedilol Teva may affect the activity of certain medicines. Similarly, certain medicines may affect the activity of Carvedilol Teva. In particular, inform the doctor or pharmacist if you are taking:
- Antihypertensives and heart medicines such as: diuretics, calcium channel blockers (e.g., diltiazem or verapamil), medicines given to control irregular heart rate (e.g., digoxin or amiodarone).
- Catecholamine-depleting medicines, e.g., reserpine and monoamine oxidase inhibitors (MAOIs) such as isocarboxide and phenelzine (to treat depression).
- Fluoxetine and paroxetine (to treat depression).
- Medicines to treat diabetes, such as insulin or metformin.
- Clonidine (to treat high blood pressure, migraine and flushing in menopausal women).
- Rifampicin (to treat infections).
- Cyclosporin (to suppress the immune system after transplantations).
- Nonsteroidal anti-inflammatory drugs (NSAIDs, such as aspirin, indomethacin and ibuprofen).
- Beta receptor agonist bronchodilators (to treat airway narrowing and wheezing due to asthma or other lung diseases (such as salbutamol and terbutaline sulfate)).

Use of the medicine and food

Take the medicine with a meal.

Use of the medicine and alcohol consumption

Use of the medicine may cause dizziness, especially when combined with alcohol.

Pregnancy and breastfeeding

Do not take Carvedilol Teva if you are pregnant, trying to become pregnant or are breastfeeding, unless instructed otherwise by a doctor.

Driving and operating machinery

Use of this medicine may cause dizziness, especially at the beginning of treatment or when treatment is modified. If this happens to you, do not drive, use tools or operate machinery. Tell your doctor if you notice other effects that may affect your driving, use of tools or machinery when taking Carvedilol Teva .

Important information about some of the ingredients of the medicine

Carvedilol Teva contains **lactose**. If you have been told by the doctor that you have an intolerance to certain sugars, refer to the doctor before using the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

The usual starting dosage is generally 3.125 mg, twice a day, for two weeks. The doctor will increase the dosage gradually, over several weeks, up to a maximal dose of 25 mg, twice a day. If you weigh more than 85 kg, the dosage can be increased to up to 50 mg, twice a day.

When discontinuing use of the medicine for a period longer than two weeks, inform the doctor. The doctor may tell you to take the starting dose again.

Elderly patients: the maximum dose per day is generally 50 mg, in divided doses.

Do not exceed the recommended dose.

Swallow the tablets with a little water. Take the medicine with a meal, at set intervals.

Carvedilol Teva 6.25 mg: the tablet can be halved on the score line.

Carvedilol Teva 12.5 mg: the tablet can be halved on the score line.

There is no information regarding crushing and chewing.

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

If you accidentally took a higher dosage, the following effects may occur: slow pulse, dizziness, shortness of breath, wheezing or severe tiredness.

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

If you forgot to take this medicine, at the required time, take a dose as soon as you remember. If it is almost time to take the next dose, skip the forgotten dose. Never take two doses together!

Adhere to the treatment regimen as recommended by the doctor.

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

If you stop taking the medicine, 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 medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS:

As with any medicine, use of Carvedilol Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately in the event of:
- Severe allergic reaction (signs can include: sudden swelling of the throat, face, lips and mouth, which may cause breathing or swallowing difficulties).
- Chest pain accompanied by shortness of breath, sweating and nausea.
- Less frequent passage of urine, with swelling of the legs, may indicate a kidney problem.
- Very low blood sugar level (hypoglycemia), which may cause seizures or unconsciousness.
- Severe skin reactions (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis) can occur in very rare cases. Symptoms can include: redness, often accompanied by blisters on the skin or on mucous membranes, such as inside the mouth, genital area or eyelids. These may first occur as circular spots, usually with blisters in the center, which may progress to extensive peeling of the skin that may be life-threatening. These severe skin reactions are sometimes accompanied by headache, fever and body aches (flu-like symptoms).

Additional side effects

Very common side effects – effects that occur in more than one user in ten:
- Dizziness, headache, weakness and tiredness – effects that are not serious and usually occur at the beginning of treatment.
- Heart problems (signs include chest pains, tiredness, shortness of breath and swelling of the arms and legs).
- Low blood pressure, manifested by, for example, dizziness.

Common side effects – effects that occur in 1-10 in 100 users:
- Infections in the airways (bronchitis), lungs (pneumonia), nose and throat (upper respiratory tract); the signs include wheezing, shortness of breath, chest tightness and sore throat.
- Urinary tract infections (which may cause problems passing urine).
- Low red blood cell count (anemia); signs include a tired sensation, pale skin, palpitations and shortness of breath.
- Weight gain.
- Increased blood cholesterol levels (measured in blood tests).
- Poor control of blood sugar levels in diabetic patients.
- Depression.
- Vision disturbances, eye pain or dryness due to reduced tear production.
- Slow pulse.
- Dizziness upon standing up.
- Fluid retention (signs include: swelling all over or of parts of the body, such as the hands, feet, ankles and legs and increased blood volume in the body).
- Blood circulation problems in the arms and legs (signs include: cold hands and feet, pallor, tingling and pain in the fingers and pain in the legs which worsens when walking).
- Breathing problems.
- Nausea, vomiting, diarrhea, stomach pain, indigestion.
- Pain – possibly in the hands and feet.
- Kidney problems, including changes in frequency of urination.
- Fainting.

Uncommon side effects – effects occurring in 1-10 in 1,000 users:
- Sleeping disturbances.
- Tingling or numbness in the hands or feet.
- Skin problems (including rash which can cover an extensive area of the body, urticaria, itching, and areas of dry skin).
- Increased sweating.
- Hair loss.
- Sexual function disturbances (impotence).
- Constipation.

Rare side effects – effects that occur in 1-10 in 10,000 users:
- Platelet deficiency in the blood, manifested by signs such as: bruising easily and nosebleed.
- Nasal congestion, wheezing and flu-like symptoms.
- Dry mouth.

Very rare side effects – effects that occur in less than one in 10,000 users:
- Low count of all types of white blood cells (signs include: infections in the mouth, gums, throat and lungs).
- Allergic reaction (hypersensitivity). Signs can include breathing or swallowing difficulties as a result of sudden swelling of the throat or face, or swelling of the hands, feet and ankles.
- Kidney problems (which are detected in laboratory tests).
- Some women may experience difficulty controlling their bladder; the effect generally improves upon discontinuation of treatment.

The medicine may cause development of signs of diabetes in patients with latent diabetes.

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

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine should be kept in a safe 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 (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 25°C.
Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains inactive ingredients:

Carvedilol Teva 6.25 mg:
Lactose monohydrate, povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, color yellow iron oxide.

Carvedilol Teva 12.5 mg:
Lactose monohydrate, povidone, crospovidone, colloidal anhydrous silica, magnesium stearate, color red iron oxide.

What the medicine looks like and the contents of the package:

Carvedilol Teva 6.25 mg:
A round, flat, light yellow to yellow tablet. On one side of the tablet there is a score line, and the other side is debossed with the letters "CVL" on the top and "T2" on the bottom.

Carvedilol Teva 12.5 mg:
A round, flat, mottled light brick red, marble-like tablet. On one side of the tablet there is a score line, and the other side is debossed with the letters "CVL" on the top and "T3" on the bottom.

Package size: 28 or 30 tablets.

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in December 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Carvedilol Teva 6.25 mg: 135.45.31252
Carvedilol Teva 12.5 mg: 135.46.31073