PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Dilatam 120 SR

Slow-release tablets

Composition

Each tablet contains:

Diltiazem (as hydrochloride) 120 mg

For information about inactive ingredients see section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of hypertension and angina pectoris.

Therapeutic class: calcium channel blockers.

These tablets have been prescribed for you for treatment of angina pectoris (chest pain caused by insufficient amount of oxygen reaching the heart) or for treatment of high blood pressure (hypertension). The tablets contain the active ingredient diltiazem, which helps more blood reach the heart and reduces blood pressure.

Dilatam 120 SR tablets were designed to work well for 12 hours. If the tablets are crushed or chewed, the dosage that was supposed to last for 12 hours may be absorbed rapidly in your body. This may be dangerous and cause serious problems, such as an overdose.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are pregnant or there is a possibility that you might become pregnant.
- You have an irregular or severely slow heartbeat (slowing of the heartbeat to less than 40 beats per minute).
- You have heart failure (a condition that may cause shortness of breath and swollen ankles) or problems with blood flow to the lungs.
- You are taking a medicine that contains the active ingredient lomitapide, which is used for the treatment of high cholesterol levels (see section "Drug interactions").

Special warnings regarding the use of the medicine

Before treatment with Dilatam 120 SR, inform the doctor if:

- You have a liver or kidney problem. The doctor may follow your condition closely.
- You have some other cardiac problem besides angina pectoris and besides the problems mentioned above.
- You have porphyria (a rare disease of the blood's pigment).
- You have intestinal problems.
- You have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. Since cases of kidney injury have been reported in patients with such conditions, the doctor may need to monitor your kidney function.

Children

This medicine is not intended for children.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. If you are taking Dilatam 120 SR with certain other medicines, the effect of this medicine or of the other medicines may be altered.

In particular, do not take this medicine and tell your doctor if you are taking:

Medicines that contain lomitapide, which are used for the treatment of high cholesterol levels. Dilatam 120 SR may increase the concentration of lomitapide and this may lead to an increase in the probability and severity of side effects related to the liver.

Inform the doctor or pharmacist if you are taking:

- Another medicine for treatment of high blood pressure, such as beta blockers (e.g., atenolol), diuretics (e.g., bendroflumethiazide) or ACE inhibitors (e.g., captopril or enalapril).
- Medicines of the alpha-blockers group, given for treatment of high blood pressure or prostate problems (e.g., prazosin).
- Any medicine that may cause low blood pressure or slowing of heart rate (e.g., aldesleukin for treatment of renal cancer, or antipsychotics for treatment of mental and behavioral problems).
- Ivabradine for treatment of angina pectoris.
- Antiarrhythmic medicines for treatment of irregular or rapid heartbeat (e.g., digoxin, amiodarone or beta blockers).
- Cilostazol for treatment of intermittent claudication (a condition that causes leg pain due to decreased blood supply to the muscles).
- Medicines of the statins group for lowering blood cholesterol level (e.g., simvastatin, atorvastatin).
- Medicines of the H_2 blockers group for treatment of stomach ulcer, digestive difficulties and heartburn (e.g., cimetidine and ranitidine).
- Carbamazepine or phenytoin for treatment of convulsions, spasms or seizures.
- Medicines of the benzodiazepines group for treatment of anxiety or for sleep induction (including, e.g., midazolam).
- Medicines of the barbiturates group for treatment of convulsions or for sleep induction (including, e.g., phenobarbital or primidone).
- Antidepressants, such as tricyclic antidepressants (including, e.g., amitriptyline or imipramine) or lithium.
- Rifampicin for treatment of tuberculosis.
- Cyclosporine, sirolimus or tacrolimus for prevention of transplant rejection or for treatment of other problems of the immune system.
- Certain medicines of the protease inhibitors group for treatment of HIV (including, e.g., atazanavir or ritonavir).
- Dantrolene (a muscle relaxant).
- Theophylline for treatment of breathing problems, such as asthma.
- Medicines of the nitrate derivatives group for treatment of angina pectoris or hypertension (including, e.g., glyceryl trinitrate or isosorbide mononitrate).
- Steroidal medicines for treatment of inflammation or allergies (e.g., methylprednisolone).

If you are about to undergo general anesthesia, inform the doctor that you are taking this medicine, as this medicine may augment the effect of the general anesthesia.

Use of the medicine and alcohol consumption

Do not take Dilatam 120 SR together with alcohol.

Pregnancy and breastfeeding

Do not take Dilatam 120 SR if you are pregnant or might become pregnant.

Avoid breastfeeding while using the medicine. If taking this medicine is medically essential, you should choose an alternative way for feeding your baby.

Consult with your doctor or pharmacist before taking any medicine.

Driving and operating machinery

The medicine may cause several side effects, such as dizziness and general malaise. These effects may affect your ability to drive (see section 4 for a full list of side effects) and they are usually felt primarily in the beginning of treatment with the medicine, or upon increasing the dosage. If the medicine affects you in such a way, do not drive or operate machinery.

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 how to use the preparation.

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

This medicine should be taken at set intervals as determined by the treating doctor.

Adults: The generally accepted dosage is one tablet of 120 mg twice a day.

The dosage is individually determined by the doctor and is tailored to the needs of the patient.

The medicine is not intended for children.

Do not exceed the recommended dose.

How to take the medicine

Swallow the tablet whole with a glass of water.

Crushing/halving/chewing

Do not chew, crush or halve the tablet, in order not to harm its mode of action. The tablet is designed to work for 12 hours when swallowed whole. If the tablet is broken, crushed, dissolved or chewed, the entire 12-hour dose may be absorbed rapidly in your body. This may be dangerous and cause serious problems, such as an overdose.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

People who have taken an overdose of this medicine may feel bad and suffer from the following effects: weakness, slow heartbeat, decreased kidney function and loss of consciousness.

If you forget to take this medicine at the required time

If you remember within 4 hours of the scheduled time for taking the medicine, take the medicine immediately and take the next dose at the usual time.

If more than 4 hours have passed since the scheduled time for taking the medicine, consult with the doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

Do not stop taking the medicine unless the doctor instructs you to. If you want to stop using the medicine, consult with the doctor first.

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

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

4. SIDE EFFECTS

As with any medicine, using Dilatam 120 SR may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Look out for the following severe allergic reactions. They have occurred in a small number of people, but their exact incidence cannot be estimated:

- An allergic reaction (hypersensitivity), including swelling of the face or throat.
- Rash or itching, especially those that cover the entire body, severe exfoliation, blisters or skin peeling, with or without fever (known as Stevens-Johnson syndrome).

Contact the doctor immediately if any of these effects occurs.

Additional side effects

Very common side effects (may occur in more than 1 out of 10 patients):

- Swelling of the hands, ankles or feet.

Common side effects (may occur in 1-10 out of 100 patients):

- Nausea, abdominal pain, digestive difficulties, constipation.
- Dizziness, headache.
- Flushing or skin redness, itch.
- Rapid, slow or irregular heartbeat.
- General malaise.
- Tiredness.

Uncommon side effects (may occur in 1-10 out of 1,000 patients):

- Diarrhea, vomiting.
- Sensation of weakness, especially when standing up.
- Nervousness.
- Sleeping difficulties.
- Worsening of liver function tests (can be observed in blood tests).

Rare side effects (may occur in 1-10 out of 10,000 patients):

- Dry mouth.
- Raised, itchy rash (urticaria).

Side effects with unknown incidence (incidence cannot be estimated from existing data):

- Heart failure that may cause shortness of breath or swollen ankles.
- Hepatitis.
- Changes in muscle tone and/or movement disorders.
- Mood changes, including depression.
- Skin problems, such as increased sensitivity to sunlight.
- A decrease in blood platelet level, which increases the risk for bleeding and bruising.
- Enlarged breasts in men.
- Bleeding, sensitivity or enlargement of the gums.
- Inflammation of blood vessels (often accompanied by skin rash).
- Sweating.
- Low blood pressure.
- A condition in which the body's defense system attacks normal tissue, causing symptoms such as joint swelling, tiredness and rash (lupus-like syndrome).

You might see the tablet's remains in your stool. This should not affect the way the medicine works.

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

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store in a dry and dark place below 25°C.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard 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:

Tablet contents:

Hydroxypropyl methyl cellulose, povidone, hydroxypropyl cellulose, talc, polyethylene glycol 6000, colloidal silicon dioxide, hydrogenated vegetable oil, magnesium stearate, polyethylene glycol 4000.

What does the medicine look like and what are the contents of the package:

A round, cream-white, film-coated tablet, debossed with "120" on one side and "D" on the other side.

Each pack contains 10, 30 or 60 tablets in a blister pack.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020, Israel.

This leaflet was revised in July 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 057.29.26825

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