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

The medicine is dispensed with a doctor's prescription only.

Cilaril Plus

Tablets

Composition: Each tablet contains:

Cilazapril 5 mg

Hydrochlorothiazide 12.5 mg

For the list of inactive and allergenic ingredients, please see section 6: "Further information".

Read the 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 to treat you. 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?

The medicine is intended for the treatment of hypertension in patients who have been stabilized on the components of this preparation given in the same proportions.

Therapeutic group:

Cilazapril: Angiotensin Converting Enzyme (ACE) inhibitor

Hydrochlorothiazide: a diuretic

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are pregnant or breastfeeding.
- There is a known sensitivity to any of its ingredients or to other medicines from the ACE inhibitors group, to thiazides (diuretics), or to medicines that contain sulfonamide derivatives.
- You have suffered in the past from angioedema (swelling of the face, tongue, throat) after treatment with other medicines from the ACE inhibitors group.
- You suffer from ascites (fluids in the abdominal cavity).
- You suffer from urinary retention.
- You suffer from diabetes and are being treated with antihypertensives that contain aliskiren.

Special warnings regarding use of the medicine

Before treatment with Cilaril Plus, tell the doctor if:

- You have suffered in the past from skin cancer, or if you develop an unexpected lesion on the skin while using the medicine. Use of hydrochlorothiazide may increase the risk of developing cancer of the skin and lips (non-melanoma skin cancer), especially with long-term use of high dosages. Protect the skin from exposure to the sun and ultraviolet (UV) radiation while using **Cilaril Plus**.
- You are suffering, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the liver, the kidney/urinary tract, if you are suffering from cough, diabetes, hyperkalemia (characterized by effects such as confusion, irregular heart rate, nervousness, numbness or tingling in the hands, feet or lips, shortness of breath or breathing difficulties, weakness or heaviness in the legs), from gout, from an increase in blood lipid levels (cholesterol and triglycerides), from an increased loss of fluids (diarrhea or vomiting).
- You intend to become pregnant during the course of treatment, you must consult the doctor about continuing treatment.
- You are a patient on a low-sodium diet, a patient undergoing dialysis, a patient suffering from lupus.
- Inform the doctor if you have kidney function problems and are being treated with antihypertensives containing aliskiren.
- This medicine may cause very low blood pressure. With the first dose, there may be an increased effect of the medicine, manifested by a drop in blood pressure; therefore, it is recommended to take the first dose while lying down.

  Note that excessive perspiration and loss of fluids, such as vomiting or diarrhea, may cause hypotension – in such cases, be sure to drink adequately.
- You are sensitive to any food or medicine, inform the doctor before taking the medicine.
- You are due to undergo surgery (including dental) or a procedure involving anesthesia, inform the doctor (anesthesiologist) that you are taking this medicine.
- Do not use potassium supplements or potassium-containing salt substitutes without first consulting the doctor.

This medicine is generally not intended for children and infants.

Tests and follow up:

Before starting treatment and during the course of treatment with this medicine, blood, urine and kidney function tests should be performed, as well as monitoring for hypertension.

The medicine may affect blood and urine test results. Inform the doctor before you perform these tests.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking: aliskiren (to lower blood pressure), other antihypertensives, cough and cold medicines, diuretics, non-steroidal anti-inflammatory drugs (NSAIDs, such as aspirin), lithium (for bipolar disorder), antacids, corticosteroids, cholesterol-lowering medicines whose source is resin (cholestyramine and colestipol), muscle relaxants, medicines that may cause a rise in blood pressure (such as adrenaline), barbiturates, narcotic analgesics, potassium-containing preparations (such as salt substitutes), medicines for treatment of diabetes (insulin, oral preparations), allopurinol (for gout), cytostatic medicines/immunosuppressants, procainamide (for the heart), digitalis, if you are undergoing treatment for bee or wasp stings.

Use of the medicine and alcohol consumption:

Do not drink wines or alcoholic beverages during the course of treatment with the medicine, as it may cause very low blood pressure.

Driving and operating machinery:

Use of this medicine may impair alertness or cause dizziness, especially at the beginning of treatment, and therefore caution should be exercised when driving a car, operating dangerous machinery, and any activity that requires alertness.

Important information about some of the ingredients of the medicine:

The preparation contains lactose and may cause an allergy among people sensitive to lactose.

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.

Do not exceed the recommended dose.

If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

Swallow the medicine with a bit of water, before or after a meal. It is preferable to take the medicine approximately at the same time every day, preferably in the morning.

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 designated time, take a dose as soon as you remember, but never take two doses together!

How can you contribute to the success of the treatment?

Complete 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.

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 the doctor or pharmacist.

4. SIDE EFFECTS

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

In addition to the desired activity of the medicine, side effects may occur while using it, for example: headache, rash, diarrhea, nausea, dizziness, tiredness, digestive disturbances, change in taste, lack of appetite, muscle/joint pains, cough, sore throat, hair loss, increased sensitivity to light, increased sweating, impotence, flushing, sleep disturbances.

These side effects usually disappear within a short time following the period of adaptation to the preparation.

Side effects that require special attention:

A decrease in red blood cells, white blood cells or platelets, tongue pain, sinusitis, severe skin problems (including blisters or peeling), loosening of nails, breast enlargement in men (rare): refer to the doctor immediately!

Edema in various organs, including: lips, eyes, tongue, and breathing difficulties (rare): refer to the doctor immediately!

Hypotension (manifested by dizziness or fainting and may lead to heart attack), chest pain, rapid or irregular heart rate, frequent or painful urination, breathing difficulties or coughing up blood, signs of stroke (such as numbness of the face, arms and legs, difficulty speaking, understanding or swallowing, loss of vision, sudden headache), sudden abdominal pain (intestinal angioedema) or pancreatitis (rare): refer to the doctor immediately!

Anaphylactic shock effects (such as nausea, headache, rash, shortness of breath, low blood pressure, slowed heart rate): refer to the doctor immediately!

Severe nausea and vomiting, severe diarrhea, signs of infection (such as sore throat, fever), muscle or joint pain, yellowing of the skin or eyes (liver problems) (rare): refer to the doctor immediately!

Side effect of unknown frequency (frequency can not be estimated from the information available): cancer of the skin and lips (non-melanoma skin cancer).

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 with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects from drug treatment", found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects. Alternatively, you can report to "Unipharm Ltd".

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 in order 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: Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Lactose anhydrous, Maize starch, Hydroxypropyl methylcellulose, Sodium stearyl fumarate, Opadry brown OY-9375, Opadry white Y-1-7000.

Each **Cilaril Plus** tablet contains 173 mg lactose.

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

Cilaril Plus is packaged in trays (blister), inserted in a carton package. Each package contains 7, 10, 14, 15, 28, 30 tablets. Not all package sizes may be marketed.

Cilaril Plus tablets are film-coated, light brown, round, and biconvex, with a score line on one side.

License holder: Unipharm Ltd., P.O.B. 21429, Tel Aviv, 6121301.

Manufacturer and address: Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in July 2012 and was updated in accordance with the Ministry of Health guidelines in February 2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Cilaril Plus: 135 95 31365 00

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