

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**  
The medicine is dispensed with a doctor's prescription only

## Candor Plus Tablets

### Composition:

Each **Candor Plus** tablet contains:

Candesartan cilexetil 16 mg  
Hydrochlorothiazide 12.5 mg  
For inactive ingredients, please see section 6 - "Further Information".

**Read the leaflet carefully in its entirety before using the medicine.**

Keep the leaflet; you may need it again.

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 the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is not intended for children and adolescents below 18 years of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

**Candor Plus** is intended for treatment of hypertension when treatment with candesartan or hydrochlorothiazide alone is not sufficient.

### Therapeutic group:

Candesartan cilexetil is a medicine belonging to the angiotensin II receptor inhibitors group and works by blocking the effects of the hormone angiotensin II, leading to dilation of the blood vessels and to lowering of blood pressure.

Hydrochlorothiazide is a medicine that belongs to the group of preparations called diuretics.

The medicine works by removing sodium chloride salt and water through the urinary system thus causing lowering of blood pressure.

### 2. BEFORE USING THE MEDICINE

#### ❗ Do not use the medicine if:

- You are allergic to the active ingredients candesartan cilexetil or hydrochlorothiazide, or to any of the inactive ingredients (see section 6).
- You are more than three months pregnant (it is preferable to avoid using the medicine even in the beginning of pregnancy. For further information, see "Pregnancy and breastfeeding" section below).
- You have a known sensitivity to medicines from the sulfonamide class. Consult with a doctor if you are uncertain.
- You suffer from gout.
- You suffer from severe liver or kidney problems, or biliary tract obstruction.
- In case of fluid or electrolyte imbalances (e.g., low levels of potassium chloride or high levels of sodium).
- You are taking a medicine to lower blood pressure that contains aliskiren and you have diabetes.

- You are taking a medicine to lower blood pressure that contains aliskiren and you have kidney function problems.

**Special warnings regarding use of Candor Plus:**  
❗ **Before treatment with Candor Plus, tell the doctor if:**

- You have had skin cancer in the past, 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 upon prolonged use at high dosages. Protect the skin from exposure to the sun and ultraviolet (UV) rays while using **Candor Plus**.
- You are suffering from impaired function of the heart, the liver or the kidneys.
- You have diabetes.
- You have SLE (lupus).
- You have recently undergone a kidney transplantation.
- You are suffering from diarrhea and vomiting or have recently had severe vomiting.
- You are suffering from a disease called primary hyperaldosteronism, if you suffer from an adrenal gland disease called Conn's syndrome.
- You have low blood pressure.
- You have ever had a stroke.
- You have suffered in the past from asthma or an allergy.
- You are due to undergo surgery. Tell the doctor or dentist that you are taking **Candor Plus**. **Candor Plus** in combination with anesthetics may cause a drop in blood pressure.
- You are sensitive to any food or medicine, inform the doctor before taking the medicine.
- You are taking any of the following medicines used to treat hypertension:
  - ACE inhibitors (e.g., enalapril, lisinopril and ramipril), especially if you are suffering from diabetes-related kidney problems.
  - Aliskiren.

In this case, the doctor may have to check and monitor the following measures - kidney function, blood pressure and electrolyte levels (e.g., potassium) in the blood at regular time intervals.

The doctor may want to meet more frequently if any of the conditions listed above are applicable.

**Candor Plus** may cause skin hypersensitivity upon exposure to the sun.

#### ❗ If you are taking other medicines

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

- Do not use **Candor Plus** if you are taking a medicine to lower blood pressure that contains aliskiren and you have diabetes.
- Do not use **Candor Plus** if you are taking a medicine to lower blood pressure that contains aliskiren and you have kidney function problems.

In particular, inform the doctor or the pharmacist if you are taking:

- Medicines to lower blood pressure - beta blockers, aliskiren-containing medicines, diazoxide and ACE inhibitors such as - enalapril, captopril, lisinopril and ramipril.

- Potassium supplements or salt substitutes containing potassium (medicines that may increase the levels of potassium in the blood).
- Heparin (a medicine used to thin the blood).
- Diuretics, to remove fluids from the body.
- Laxatives.
- Penicillin or a combination of two medicines to treat bacterial infection - trimethoprim and sulfamethoxazole.
- Non-steroidal anti-inflammatory drugs (NSAIDs) also used to relieve pain, such as - aspirin (if you are taking more than 3 grams each day), ibuprofen, naproxen, diclofenac, etoricoxib, celecoxib.
- Colestipol or cholestyramine (cholesterol-lowering medicines).
- Amphotericin (an antibiotic used for the treatment of a widespread fungal infection).
- Lithium (a medicine used to treat mental problems).
- Calcium supplements or vitamin D.
- Beta blockers, digoxin (preparations to regulate heart rhythm).
- Anticholinergic preparations (e.g., atropine, biperiden).
- Cytotoxic preparations (e.g., cyclophosphamide, methotrexate), medicines to treat cancer.
- Steroids such as - prednisone.
- Adrenal hormone (ACTH).
- Amantadine (for the treatment of Parkinson's or viral infections).
- Barbiturates (medicines to treat epilepsy or as a sedative).
- Antipsychotic medicines that may affect blood potassium levels.
- Carbenoxolone (a medicine used to treat esophageal diseases or oral ulcers).
- Anti-diabetic medicines (including insulin).
- Cyclosporine (a medicine used to prevent organ rejection after an organ transplant).
- Other medicines that may lead to enhancement of the antihypertensive effect, such as baclofen (muscle relaxant), amifostine (a medicine to treat cancer) and certain antipsychotic medicines.
- Contrast agents that contain iodine intended for imaging.

#### ❗ Use of the medicine and food:

The medicine can be taken without regard to meals.

#### ❗ Use of the medicine and alcohol consumption:

Talk to the doctor about alcohol consumption habits. Some people taking **Candor Plus** may feel dizzy and faint when consuming alcohol.

#### ❗ Pregnancy and breastfeeding:

- Tell the doctor if you are pregnant, think you are pregnant or are planning to become pregnant during treatment.

The doctor will usually advise you to stop using **Candor Plus** and to switch to another medicine **before you become pregnant** or immediately after you discover that you are pregnant. **Candor Plus** is not recommended for use in early pregnancy, and must not be taken after the third month, as it may cause serious harm to the unborn baby, if taken after the third month of pregnancy.

- If you are breastfeeding or plan to breastfeed, please inform the doctor. Breastfeeding mothers are recommended not to use **Candor Plus** while breastfeeding, especially newborns and premature babies. If you wish to breastfeed, the doctor may recommend an alternative treatment.

#### ❗ Driving and operating machinery:

This medicine may cause dizziness or fatigue in some people. If you experience these effects, avoid driving a vehicle, operating dangerous machinery and engaging in any activity that requires alertness.

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

The tablets contain lactose which is a type of sugar. If you have been told by the doctor that you suffer from an intolerance to certain sugars, consult the doctor before taking this medicine.

### 3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- The dosage and treatment regimen will be determined by the doctor only.
- Do not exceed the recommended dose.**
- This medicine is not intended for children (under the age of 18)

#### Instructions for use:

- If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.
- The medicine can be taken with or without food.
- It is recommended to take the tablets at the same time each day, for example, in the morning.
- If you forgot to take this medicine at the designated time, take the next dose as usual, but never take two doses together! If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.**
- Complete the treatment 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 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 **Candor Plus** 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.

#### Effects requiring special attention; stop taking the medicine and refer to the doctor immediately:

- Breathing and swallowing difficulties, swelling of the face, tongue, lips and/or throat.
- Acute itching accompanied by raised blisters, rapidly developing rash with blisters and peeling skin and most often blisters in the mouth, as well.
- Tendency to bruise easily, or extreme fatigue (rare).

In the event you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult the doctor immediately.

**Candor Plus** may cause a drop in the level of white blood cells. As a result, you may be less resistant to infections and you may experience fatigue, inflammations or fever. In this case, contact the doctor immediately to perform blood tests.

#### Common side effects that occur frequently (affect less than one patient out of 10):

- Decreased amount of sodium in the blood. If the reduction is severe, you may experience weakness, lack of energy or muscle cramps.
- Increase or decrease in potassium levels in the blood, especially if you have kidney problems or heart failure. If the change is severe, you may experience fatigue, weakness, heart rhythm disturbances or a prickling and tingling sensation.
- Increase in levels of cholesterol, sugar or uric acid in the blood.
- Sugar in the urine.
- Dizziness and weakness.
- Headache.
- Respiratory tract infection.

#### Uncommon side effects (affect less than one patient out of 100):

- Low blood pressure - may cause you to feel faint or dizzy.
- Loss of appetite, diarrhea, constipation, an upset stomach.
- Rash, urticaria, rash caused by sensitivity to sunlight.

#### Rare side effects (affect less than one patient out of 1,000):

- Jaundice (of the skin or whites of the eyes). If this condition occurs, refer to a doctor immediately.
- Effect on kidney function (especially if you suffer from kidney problems or heart failure).
- Difficulties sleeping, depression, restlessness.
- Tingling or prickling sensation in the arms or legs.
- Temporary blurred vision.
- Heart rhythm disturbances.
- Breathing difficulties (including lung inflammation and fluid in the lungs).
- Fever.
- Inflammation of the pancreas - causing severe abdominal pain.
- Muscle cramps.
- Damage to blood vessels, causing red or purple dots on the skin to appear.
- Decreased white blood cells, red blood cells and platelets - may be manifested by fatigue, infections, fever or bruising.
- Severe, rapidly spreading rash, with blisters or peeling of the skin, or onset of blisters in the mouth.

#### Very rare side effects (affect less than one patient out of 10,000):

- Swelling of the face, tongue, lips and/or throat.
- Itching.
- Pain in the back, joints and muscles.
- Changes in liver function, including inflammation of the liver (hepatitis). You may experience fatigue, yellowing of the skin and whites of the eyes, and flu-like symptoms.
- Cough.
- Nausea.
- The active ingredient, hydrochlorothiazide, found in **Candor Plus**, can, in certain patients, activate or worsen lupus.

#### Side effects of unknown frequency:

- Cancer of the skin and lips (non-melanoma skin cancer).
- Sudden short-sightedness.
- Sudden pain in the eyes (acute angle-closure glaucoma).
- Systemic and cutaneous lupus erythematosus (an allergic condition that causes fever, joint pain and skin rash, which can be manifested by redness, blisters, peeling and lumps on the skin).

**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.**

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](http://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 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. In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- 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 monohydrate; Hydroxypropyl cellulose; Poloxamer 188; Magnesium stearate; Iron oxide red. Each **Candor Plus** tablet contains: 160.4 mg lactose.

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

**Candor Plus** tablets are hexagonal in shape, light pink, with a score line on one side. **Candor Plus** is packaged in trays (blister) inserted into a carton package. Each package contains 28 tablets.

**Candor Plus** comes in package sizes of 5, 7, 10, 14, 20, 21, 28, 30 tablets.

Not all package sizes may be marketed.

#### Name of license holder:

Unipharm Ltd., P.O. Box 21429 Tel Aviv, 6121301.

#### Name of manufacturer and address:

Trima Ltd., Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in October 2014 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:**

**Candor Plus:** 152 75 34056 00