

Candor 8, 16 Tablets

Composition:

Each **Candor 8** tablet contains:

Candesartan cilexetil 8 mg

Each **Candor 16** tablet contains:

Candesartan cilexetil 16 mg

For a list of the 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 medical condition is similar.

The medicine is intended for adults over 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

To treat high blood pressure (hypertension) and to treat heart failure.

Therapeutic group

The medicine is an angiotensin II receptor antagonist, which blocks the effect of the angiotensin II hormone, thereby causing relaxation of the blood vessels, resulting in lowering of blood pressure. In addition, it helps the heart in circulating the blood to all parts of the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are more than three months pregnant (it is preferable to also avoid using the medicine at the beginning of pregnancy. For further information, see section "Pregnancy and breastfeeding" below).
- You have a known sensitivity to the active ingredient - candesartan cilexetil or to any of the ingredients of the medicine (see section 6 "Further Information" below).
- You suffer from severely impaired liver function or from biliary tract obstruction.
- You are taking a medicine to lower blood pressure containing aliskiren and you have diabetes.
- You are taking a medicine to lower blood pressure containing aliskiren and you have kidney function problems.

Special warnings regarding use of Candor:

Before treatment with Candor, tell the doctor if:

- You are suffering, or have suffered in the past, from impaired function of the heart, the liver, the kidney, or are undergoing dialysis.
- You have recently undergone a kidney transplant, if you suffer from diarrhea and vomiting or you have recently suffered from severe vomiting, if you suffer from a disease called primary hyperaldosteronism, if you suffer from a disease of the adrenal gland called Conn's syndrome, if you have low blood pressure, if you had a stroke in the past.
- Tell the doctor if you are pregnant, think you are pregnant or are planning to become pregnant. **Candor** is not recommended for use in the beginning of pregnancy and is prohibited for use after the third month of pregnancy since it may cause serious damage to your unborn baby (for further information, see "Pregnancy and breastfeeding" section).
- You are due to undergo an operation. Tell the doctor or dentist that you are taking **Candor**. **Candor** 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 one of the following medicines used to treat high blood pressure:
 - ACE inhibitors (such as enalapril, lisinopril and ramipril), especially if you suffer from kidney problems associated with diabetes.
 - Aliskiren.
 - You are being treated with a medicine from the ACE inhibitor group together with medicines to treat heart failure known as mineralocorticoid receptor antagonists (MRAs).

In this case, your doctor may need to check and monitor the following parameters - kidney function, blood pressure and level of electrolytes (e.g., potassium) in your blood at regular intervals.

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

It is especially important to inform the doctor or pharmacist if you are taking:

- Other medicines to lower blood pressure - including diuretics, beta-blockers, diazoxide, ACE inhibitors such as enalapril, captopril, lisinopril and ramipril.
- Diuretics, to remove fluids from the body.
- If you are being treated with medicines from the ACE inhibitor group together with medicines to treat heart failure known as mineralocorticoid receptor antagonists (MRAs), such as - spironolactone, eplerenone.
- Preparations you are using without a doctor's prescription.
- A combination of two medicines to treat a bacterial infection - trimethoprim and sulfamethoxazole (e.g., resprim).
- Non-steroidal anti-inflammatory drugs (NSAIDs) also used to relieve pain, such as ibuprofen, naproxen, diclofenac, aspirin (if you take more than 3 g a day), etoricoxib and celecoxib.
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, or other medicines that may raise the potassium level.
- Heparin - a medicine used to thin the blood.
- Lithium (a medicine used to treat mental problems).

Use of the medicine and food:

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption:

Talk to your doctor about alcohol consumption habits. Some people who take **Candor** may experience dizziness and weakness when consuming alcohol.

Pregnancy and breastfeeding:

- Tell the doctor if you are pregnant, think you are pregnant or are planning to become pregnant. The doctor will normally advise you to stop using **Candor** and to switch to another medicine before becoming pregnant or immediately after you know you are pregnant. Use of **Candor** is not recommended at the beginning of pregnancy and is prohibited after the third month, since it may cause serious damage to your unborn baby if taken after the third month of pregnancy.
- If you are breastfeeding or planning to breastfeed, please inform the doctor. Nursing mothers are advised not to use **Candor** while breastfeeding, especially with newborns and premature babies. If you want 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 have 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.
- The medicine is intended for adults over 18 years of age.

Instructions for use:

- If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.
- Swallow the medicine with water.
- 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 scheduled time, take the next dose as usual, but under no circumstances should two doses be taken together!
- **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.
- Complete the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not discontinue 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.**

The usual dosage unless instructed otherwise by the doctor, is:

To treat high blood pressure:

The usual dosage is 8 mg once a day. The doctor may increase the dosage up to a total dosage of 16 mg a day, depending on your blood pressure parameters. In some patients who have kidney problems, liver problems or those who have recently lost fluids (e.g., due to vomiting and diarrhea or use of diuretics), the doctor may recommend a lower starting dosage. Some patients may have a reduced response to the medicine, when given as the only treatment. Therefore, these patients may need a higher dosage.

To treat heart failure:

The usual starting dosage is 2 mg a day. The doctor may increase the dosage by doubling it every two weeks, up to a total dosage of 32 mg a day.

4. SIDE EFFECTS

As with any medicine, use of **Candor** 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 (rare)

Stop taking the medicine and refer immediately to a doctor if you are suffering from:

- Breathing difficulties, with or without swelling of the face, lips, tongue and throat
- Swelling of the face, lips, tongue and throat, which may cause swallowing difficulties
- Severe itching of the skin (with raised lumps)

Candor may cause a reduction 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 such an event, contact the doctor immediately to perform blood tests (to rule out agranulocytosis).

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

Common side effects, occurring frequently (affect less than one patient in 10):

- Feeling dizzy
- Headache
- Respiratory tract infection
- Low blood pressure (may cause dizziness and fainting)
- Changes in blood tests: increased blood potassium levels, especially if you suffer from kidney problems or heart failure. If this is severe, you may notice fatigue, weakness, heart rate disturbances, and a "pins and needles" sensation
- Kidney function problems, and very rarely, kidney failure

Very rare side effects (affect less than 1 in 10,000 patients):

- Swelling of the face, lips, tongue and throat
- A reduction in white or red blood cells - you may experience fatigue, an infection or a fever
- Rash, urticaria
- Itching
- Back, joint and muscle pain
- Changes in liver function, including inflammation (hepatitis), fatigue, yellowing of your skin and the whites of the eyes and flu-like symptoms
- Nausea
- Changes in blood tests - reduced blood sodium levels. If there is a severe reduction, you may notice weakness, lack of energy or muscle cramps
- Cough

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Diarrhea

If the above-mentioned side effects worsen, or if you notice side effects not listed above, please see a doctor or pharmacist.

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) that directs you to the online form for reporting side effects. Additionally, 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. In 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 ingredient, the medicine also contains:

Lactose monohydrate; Hydroxypropyl cellulose; Poloxamer 188; Magnesium stearate; Iron oxide red; Iron oxide yellow.

Each **Candor 8** tablet contains: 86.5 mg lactose.

Each **Candor 16** tablet contains: 173 mg lactose.

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

Candor is packaged in trays (blister), which are inserted into a carton package. There are 28 tablets in each package. The tablets are round, biconvex and light orange colored with a score line on one side.

Candor 8,16 comes in package sizes of 5, 7, 10, 14, 20, 21, 28, 30 tablets.

Not all package sizes may be marketed.

Registration holder and address:

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

Manufacturer and address:

Unipharm Ltd., "Mevo Carmel" Industrial Park.

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

Candor 8: 150 86 33817 01

Candor 16: 150 71 33815 01

Revised in October 2020 according to MOH guidelines.