

CANDIGEN-H TABLETS

Candesartan Cilexetil + Hydrochlorothiazide (16mg + 12.5mg)

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What CANDIGEN-H is used for

CANDIGEN-H is used for treating hypertension (high blood pressure), where a monotherapy is not sufficiently effective.

How CANDIGEN-H works

Candesartan cilexetil is a type of medicine called an angiotensin II receptor antagonist, which by blocking the effects of the hormone angiotensin II, causes relaxation of the blood vessels and results in a lowering of the blood pressure.

Hydrochlorothiazide belongs to a class of drugs called diuretics. Its effects promote the urinary excretion of sodium, chloride and water and results in a lowering of the blood pressure.

Before you use CANDIGEN-H

Do not take CANDIGEN-H if you are pregnant, think you might be pregnant or considering becoming pregnant. CANDIGEN-H may cause serious harm or even death to your baby if used during pregnancy (see Pregnancy section).

- When you must not use it

- If you are breast feeding.
- If you are allergic to any of the ingredients in CANDIGEN-H or to drugs closely related to hydrochlorothiazide.
- If you have severe liver disease.
- If you have severe kidney disease.
- If you have had gout.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure medicine containing aliskiren.

Important: You should not take CANDIGEN-H if you have had problems in the past when taking medicines containing candesartan cilexetil or hydrochlorothiazide.

CANDIGEN-H is not recommended for children.

- Before you start use it

Please talk to your doctor or pharmacist before taking this medicine:

- If you are taking other medicines to help lower your blood pressure, particularly:
 - ✓ an ACE-inhibitor (for example, enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
 - ✓ aliskiren
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking CANDIGEN-H, seek medical attention immediately.
- If you are taking any other medicines including those you have bought without a prescription.
- If you have any heart, liver or kidney problems.
- If you suffer from lactose intolerance.
- If you are you taking digitalis glycosides, antiarrhythmics, non-steroidal anti-inflammatory drugs (NSAIDs), colestipol, cholestyramine, lithium, other kaliuretic, diuretics, laxatives, amphotericin, carbenoxolone, salicylic acid derivatives, potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, or other drugs that may increase potassium levels.
- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking CANDIGEN-H. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy,

you can be at higher risk of developing this.

- If you are diabetic.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Inform your healthcare providers before taking CANDIGEN-H if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking CANDIGEN-H.

See also information under the heading "When you must not use it".

- Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor or aliskiren (see also information under the headings "When you must not use it" and "Before you start to use it").

How to use CANDIGEN-H

- How much to use

The dose is one tablet each day.

- When to use it

It is best to take your tablet at the same time each day, e.g. in the morning.

- How long to use it

Take CANDIGEN-H as directed by your healthcare provider. Do not stop taking your dose without talking to your healthcare provider.

- If you forget to use it

If you forget to take a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up.

- If you use too much (overdose)

If you take more than the recommended number of tablets, contact a doctor or

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pharmacist (chemist) as soon as possible.

While you are using it

- Things you must do

It is important to keep taking CANDIGEN-H every day and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said.

If you have the impression that the effect of CANDIGEN-H is too strong or too weak, talk to your doctor or pharmacist.

- Things you must not do

Do not stop taking your dose without talking to your healthcare provider.

Pregnancy

You must not take CANDIGEN-H if you are pregnant, might be pregnant, or are considering becoming pregnant. You must tell your doctor if you think you are (or might become) pregnant. Your doctor will ask you to stop taking CANDIGEN-H before you become pregnant or as soon as you know you are pregnant and may recommend another medicine instead of CANDIGEN-H. CANDIGEN-H may cause serious harm or even death to your baby if used during pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. CANDIGEN-H must not be used by mothers who are breast-feeding.

- Things to be careful of

Taking CANDIGEN-H with food and drink

It does not matter whether you take your tablet with or without food.

Anaesthesia and surgery

If you are going to have an operation, tell your doctor or dentist that you are taking CANDIGEN-H. CANDIGEN-H, combined with some anaesthetics, may cause a drop in blood pressure.

Driving and using machines

The treatment of high blood pressure may lead to dizziness or weariness in some patients. Make sure you are not affected in this way before driving or operating machines.

Side effects

Most people taking CANDIGEN-H do not suffer any unwanted effects. Like all medicines, some people taking CANDIGEN-H may occasionally experience unwanted effects which are usually mild and do not last for long.

Unwanted effects reported very rarely are swelling of the face, lips, tongue and/or throat, back pain, rash, hives, itching, unusual skin reactions, easy bruising, or extreme fatigue, jaundice (yellow skin and/or eyes) or increased liver tests. If you suffer from any of these effects, or if you get any other unusual or unexpected symptoms, talk to your doctor or pharmacist (chemist). If you develop swelling of the face, lips, tongue and/or throat or jaundice, or if you get unusual skin reactions, easy bruising or feel extreme fatigue, contact your doctor immediately.

Very rarely, dizziness, cough and worsening of the kidney function (especially in patients with existing kidney problems or heart failure) have been reported. Changes in your potassium, sodium and red or white blood cell levels may occur very rarely. Such changes are usually detected by a blood test. In some patients, lupus conditions may be activated or made worse by hydrochlorothiazide, one of the medicines in this drug.

Rarely, acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) has been reported.

Frequency 'not known':

- Skin and lip cancer (Non-melanoma skin cancer).
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of CANDIGEN-H

- Storage

- Store below 30°C.
- Do not take your tablets after the expiry date shown on the blister strip and carton.
- Keep your medicine in a safe place where children cannot reach it.
- Remember to return any unused medicine to your pharmacist.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Light pink, oval shape, biconvex, uncoated mottled tablets debossed with 'L3' and '02' on either side of break line on one side and break line on other side.

Packaging Available:

Blister containing 10 tablets. Such 3 blisters are packed in a carton box.

- Ingredients

Active ingredient:

- Candesartan Cilexetil
- Hydrochlorothiazide

Inactive ingredients:

- Lactose Monohydrate
- Maize Starch
- Carmellose Calcium
- Hydroxypropyl Cellulose
- Macrogol 8000
- Magnesium Stearate
- Pigment Blend PB-24880 Pink [Lactose Monohydrate and iron oxide red (E172)].

- MAL number:

MALXXXXXXXXXX

Manufacturer

Alembic Pharmaceuticals Limited (Formulation Division), Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol, Panchmahal, Gujarat – 389350 India.

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Product Registration Holder

GENPHARMA SDN. BHD.
Lot 5016, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

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1st May 2024

Serial Number

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