Package leaflet: Information for the user

Candist Plus 16mg/12.5mg Tablets

Candesartan cilexetil, hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Candist Plus is and what it is used for
The name of your medicine is Candist Plus. It is used for treating high blood pressure (hypertension) in adult patients. It contains two active ingredients: candesartan cilexetil and hydrochlorothiazide. These work together to lower your blood pressure.

Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists. It makes your blood vessels relax and widen. This helps to lower your blood pressure. Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine. This helps to lower your blood pressure.

Your doctor may prescribe Candist Plus if your blood pressure has not been properly controlled by candesartan cilexetil or hydrochlorothiazide alone.

2. What you need to know before you take Candist Plus
DO NOT take Candist Plus if:
- you are allergic to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- you are allergic to sulfonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- you are more than 3 months pregnant (it is also better to avoid Candist Plus in early pregnancy – see pregnancy section).
- you have severe kidney problems.
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- you have severe liver disease or biliary obstruction (a problem with the drainage of bile from the gall bladder).
- you have persistently low levels of potassium in your blood.
- you have persistently high levels of calcium in your blood.
- you have ever had gout.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Candist Plus.

Warnings and precautions
Talk to your doctor or pharmacist before taking Candist Plus if:

- you have diabetes.
- you have heart, liver or kidney problems.
- you have recently had a kidney transplant.
- you are vomiting, have recently had severe vomiting, or have diarrhoea.
- you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- you have ever had a disease called systemic lupus erythematosus (SLE)
- you have low blood pressure
- you have ever had a stroke.
- you have ever had allergy or asthma.
- you must tell your doctor if you think you are (or might become) pregnant. Candist Plus is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril, etc.), in particular if you have diabetes-related kidney problems.
  - aliskiren
- 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 Candist Plus.
- 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 Candist Plus. 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.
- 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 Candist Plus, seek medical attention immediately.

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

See also information under the heading "DO NOT take Candist Plus".

Your doctor may want to see you more often and do some tests if you have any of these conditions.

If you are going to have an operation, tell your doctor or dentist that you are taking Candist Plus. This is because Candist Plus, when combined with some anaesthetics, may cause an excessive drop in blood pressure.

Candist Plus may cause increased sensitivity of the skin to sun.

Children and adolescents
There is no experience with the use of candesartan/HCTZ in children (below the age of 18 years). Therefore Candist Plus should not be given to children.

Other medicines and Candist Plus
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Candist Plus can affect the way some other medicines work and some medicines can have an effect on Candist Plus. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell your doctor if you are using any of the following medicines as your doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower your blood pressure, including beta-blockers, aliskiren-containing medicines, diazoxide and Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, captopril, lisinopril or ramipril (see also information under the headings "DO NOT take Candist Plus" and "Warnings and precautions").
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Calcium or Vitamin D supplements.
- Medicines to lower your cholesterol, such as colestipol or cholestyramine.
- Medicines for diabetes (tablets or insulin).
- Medicines to control your heart beat (antiarrhythmic agents) such as digoxin and beta-blockers.
- Medicines that can be affected by potassium blood levels such as some antipsychotic medicines.
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Laxatives.
- Penicillin or co-trimoxazole also known as trimethoprim/sulfamethoxazole (antibiotic medicines).
- Amphotericin (for the treatment of fungal infections).
- Lithium (a medicine for mental health problems).
- Steroids such as prednisolone.
- Pituitary hormone (ACTH).
- Medicines to treat cancer.
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Barbiturates (a type of sedative also used to treat epilepsy).
- Carbenoxolone (for treatment of oesophageal disease, or oral ulcers).
- Anticholinergic agents such as atropine and biperiden.
- Cyclosporine, a medicine used for organ transplant to avoid organ rejection.
- Other medicines that may lead to enhancement of the antihypertensive effect such as baclofen (a medicine for relief of spasticity), amifostine (used in cancer treatment) and some antipsychotic medicines.

Candist Plus with food, drink and alcohol

- You can take Candist Plus with or without food.
- When you are prescribed Candist Plus, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Candist Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Candist Plus. Candist Plus is not recommended during early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Candist Plus is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Some people may feel tired or dizzy when taking Candist Plus. If this happens to you, do not drive or use any tools or machines.

Candist Plus contains lactose and sodium
If you have been told by doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Candist Plus
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is important to keep taking Candist Plus every day.

The recommended dose of Candist Plus is one tablet once a day.
Swallow the tablet with a drink of water.

Try to take the tablet at the same time each day. This will help you to remember to take it.

If you take more Candist Plus than you should
If you take more Candist Plus than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take Candist Plus
Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

If you stop taking Candist Plus
If you stop taking Candist Plus, your blood pressure may increase again. Therefore do not stop taking Candist Plus without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be. Some of the side effects of Candist Plus are caused by candesartan cilexetil and some are caused by hydrochlorothiazide.

Stop taking Candist Plus and seek medical help immediately if you have any of the following allergic reactions:
- difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat.
- swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing.
- severe itching of the skin (with raised lumps).

Candist Plus may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Candist Plus has had any effect on your blood (agranulocytosis).

Stop taking Candist Plus and seek medical help immediately if you notice the following side effect:
Very rare (may affect up to 1 in 10,000 people):

- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

Other possible side effects include:
Common (may affect up to 1 in 10 people)
- Changes in blood test results:
  - A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.
  - An increased or reduced amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe, you may notice tiredness, weakness, irregular heartbeat or pins and needles.
  - An increased amount of cholesterol, sugar or uric acid in your blood.
- Sugar in your urine.
- Feeling dizzy/spinning sensation or weak.
- Headache.
- Respiratory infection.

Uncommon (may affect up to 1 in 100 people)
- Low blood pressure. This may make you feel faint or dizzy.
- Loss of appetite, diarrhoea, constipation, stomach irritation.
- Skin rash, lumpy rash (hives), rash caused by sensitivity to sunlight.

Rare (may affect up to 1 in 1,000 people)
- Jaundice (yellowing of the skin or the whites of your eyes). If this happens to you, contact your doctor immediately.
- Effects on how your kidneys work, especially if you have kidney problems or heart failure.
- Difficulty in sleeping, depression, being restless.
- Tingling or prickling in your arms or legs.
- Blurred vision for a short time.
- Abnormal heart beat.
- Breathing difficulties (including lung inflammation and fluid in the lungs).
- High temperature (fever).
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Muscle cramps.
- Damage to blood vessels causing red or purple dots in the skin.
- A reduction in your red or white blood cells or platelets. You may notice tiredness, an infection, fever or easy bruising.
- A severe rash, that develops quickly, with blistering or peeling of the skin and possibly blistering in the mouth.

Very rare (may affect up to 1 in 10,000 people)
- Swelling of the face, lips, tongue and/or throat.
- Itching.
- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.
- Cough
- Nausea.

Not known (frequency cannot be estimated from the available data)
- Sudden short-sightedness
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)

- Systemic and cutaneous lupus erythematosus (allergic condition which causes fever, joint pain, skin rashes which may include redness, blistering, peeling and lumps)
- Diarrhoea
- Skin and lip cancer (non-melanoma skin cancer)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Candist Plus
- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use Candist Plus after the expiry date which is stated on the carton or blister pack. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Candist Plus contains
The active substances are candesartan cilexetil and hydrochlorothiazide. Each tablet contains 16 mg of Candesartan cilexetil and 12.5 mg of Hydrochlorothiazide.

The other ingredients are Lactose monohydrate, Maize starch, Hydroxypropyl cellulose, Croscarmellose sodium, Magnesium stearate and Triethyl citrate.

What Candist Plus looks like and contents of the pack
Candist Plus are white biconvex tablets with a score line on one side and embossing CH16 on the same side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes:
7, 7x1 (single dose unit), 10, 10x1 (single dose unit), 14, 14x1 (single dose unit), 28, 28x1 (single dose unit), 30, 30x1 (single dose unit), 50, 50x1 (single dose unit), 56, 56x1 (single dose unit), 90, 90x1 (single dose unit), 98, 98x1 (single dose unit), 100, 100x1 (single dose unit), 112, 112x1 (single dose unit), 126, 126x1 (single dose unit), 140, 140x1 (single dose unit), 154, 154x1 (single dose unit), 168, 168x1 (single dose unit), 182, 182x1 (single dose unit), 196, 196x1 (single dose unit) tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:
Siegfried Malta Ltd, HHF070 Hal Far Industrial Estate, Hal Far BBG3000, Malta
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
LAMP SAN PROSPERO S.p.A., Via della Pace, 25/A, 41030 San Prospero, Modena, Italy
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Candesartan / HCT STADA 8 mg /12,5 mg and 16 mg /12,5 mg Tabletten

Belgium	Candesartan Plus HCT EG 16 mg/12,5 mg tabletten
Denmark:	Atastad Comp
Finland:	Candestad comp
Germany:	Candesartan / HCT STADA 8/12,5 mg and 16/12,5 mg Tabletten
Luxembourg:	Candesartan Plus EG 16 mg/12,5 mg comprimés
Ireland:	Candist Plus 16 mg/12.5 mg tablets
Italy:	CANDESARTAN IDROCLOROTIAZIDE EG 8/12.5 mg and 16/12.5 mg compresse
Portugal:	Candesartan + Hidroclorotiazida Ciclum
Spain:	Candesartán cilexetilo / Hidroclorotiazida STADA 16/12,5 mg comprimidos EFG
Slovakia:	Stadacand Plus
Sweden:	Atastad Comp 16/12,5 mg tabletter

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