

Approved Patient Information Leaflet for Medicines for Human Use:

CANURETIC

SCHEDULING STATUS: S3

CANURETIC

Each tablet contains 16 mg candesartan cilexetil and

12,5 mg hydrochlorothiazide

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking CANURETIC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CANURETIC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CANURETIC is and what it is used for
2. What you need to know before you take CANURETIC
3. How to take CANURETIC
4. Possible side effects
5. How to store CANURETIC
6. Contents of the pack and other information

1. What CANURETIC is and what it is used for

CANURETIC 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.

2. What you need to know before you take CANURETIC

Do not take CANURETIC:

- If you are allergic (hypersensitive) to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of CANURETIC (see section 6).
- If you are allergic to sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- If you are more than 3 months pregnant (it is also better to avoid CANURETIC in early pregnancy – see pregnancy section).
- If you have severe kidney problems or renal artery stenosis (a problem with the blood flow to the kidneys).
- If you have severe liver disease or biliary obstruction (a problem with the drainage of bile from the gall bladder).
- If you have persistently low levels of potassium in your blood.
- If you have persistently high levels of calcium in your blood.
- If you have ever had gout.
- If you suffer from a condition called “angioedema”, a condition that causes areas of your body to swell (limbs, face), difficulty digesting, and / or difficulty breathing.
- If you have ever taken medicines called “ACE-inhibitors” for a condition called “angioedema”.

- If you suffer from a condition called “Hypertrophic obstructive cardiomyopathy (HOCM)”, a condition where the heart muscles becomes abnormally thick, you may have shortness of breath, chest pain or abnormal heart beat.
- If you suffer from a condition called “Aortic stenosis” (a narrowing in your heart valves which decreases blood flow to the body).
- If you suffer from a condition called “Porphyria”.
- If you suffer from a condition called “Addison’s disease”.
- If you taking a medicine called “Lithium”.
- If you are taking a medicine that contains aliskire.
- If you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Talk to your doctor or pharmacist before taking CANURETIC:

- If you have diabetes.
- If you have heart, liver or kidney problems.
- If you have recently had a kidney transplant.
- If you had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, as in CANURETIC, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking CANURETIC.

- If you are vomiting, have recently had severe vomiting, or have diarrhoea.
- If you have a disease of the adrenal gland called Conn’s syndrome (also called primary hyperaldosteronism).
- If you have ever had a disease called systemic lupus erythaematosus (SLE)
- If you have low blood pressure
- If you have ever had a stroke.
- If you have ever had allergy or asthma.

Austell Pharmaceuticals (Pty) Ltd, 49/7.1.3/0054, CANURETIC, 16/12,5 mg, Tablets

- you must tell your doctor if you think you are (or might become) pregnant. CANURETIC 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).

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 CANURETIC.

This is because CANURETIC, when combined with some anaesthetics, may cause a drop in blood pressure.

CANURETIC may cause increased sensitivity of the skin to sun.

Children and adolescents

CANURETIC should not be given to children.

Other medicines and CANURETIC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are using any of the following medicines:

- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Oral contraceptives.
- Medicines for diabetes (tablets or insulin).
- Warfarin.
- Water tablets (diuretics).

- Laxatives.
- Penicillin (an antibiotic).
- Amphotericin (for the treatment of fungal infections).
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- Medicines to control your heartbeat (antiarrhythmic agents) such as digoxin and beta-blockers.
- Lithium (a medicine for mental health problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Medicines to lower your cholesterol, such as colestipol or cholestyramine.
- Anticholinergic agents such as atropine and biperiden.
- Calcium or Vitamin D supplements.
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Medicines to treat cancer.
- Pituitary hormone (ACTH).
- Barbiturates (a type of sedative also used to treat epilepsy).

CANURETIC with food, drink and alcohol

- You can take CANURETIC with or without food.

Pregnancy and breastfeeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking CANURETIC before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of CANURETIC. CANURETIC is not recommended during 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. CANURETIC is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Driving and using machines

Some people may feel tired or dizzy when taking CANURETIC. If this happens to you, do not drive or use any tools or machines.

It is not always possible to predict to what extent CANURETIC may interfere with your daily activities. You must ensure that they do not engage in dangerous activities (for instance driving a car or using machines) until you are aware of the measure to which CANURETIC affects you.

CANURETIC contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CANURETIC

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor or pharmacist has told you. Your doctor will tell you how long your treatment with CANURETIC will last. Do not stop early treatment. If you have the impression that the effect of CANURETIC is too strong or too weak, tell your doctor or pharmacist. You should check with your doctor or pharmacist if you are not sure.

Dosage

Take one (1) tablet of CANURETIC once a day.

Usually it takes 4 weeks to control your blood pressure.

You can take CANDESARTAN PLUS 16 / 12,5 mg AUSTELL with or without food.

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.

Use in children and adolescents with high blood pressure

CANDESARTAN PLUS 16 / 12,5 mg AUSTELL must not be given to children as safety and efficacy has not been established.

If you take more CANURETIC than you should

If you take more CANURETIC than you should, you may experience symptoms such as feeling dizzy, feeling thirsty, low blood pressure, feeling sedated and / or muscle cramps.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CANURETIC

Do not take a double dose to make up for a forgotten tablet.

If you stop taking CANURETIC

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

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

4. POSSIBLE SIDE EFFECTS

CANURETIC can have side effects.

Not all side effects reported for CANURETIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CANURETIC, please consult your health care provider for advice.

Some of the side effects of CANURETIC are caused by candesartan cilexetil and some are caused by hydrochlorothiazide.

Stop taking CANURETIC immediately and seek medical help 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).

These are all very serious side effects. If you have them, you may have had a serious reaction to CANURETIC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Tiredness, an infection or fever.
- Chest pain.
- Angina.
- Changes in the way your heart beats (for example, if you notice it beating faster, or slower).
- Difficulty breathing.

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

CANURETIC 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 Candesartan cilexetil has had any effect on your blood (agranulocytosis).

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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 or spinning sensation or weak.
- Headache.

Less frequent side effects:

- 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.
- Urinating (running to the toilet), more often than normal.
- Difficulty in sleeping, depression, being restless.

- Tingling or prickling in your arms or legs.
- Blurred vision for a short time.
- Breathing difficulties (including lung inflammation and fluid in the lungs).
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Damage to blood vessels causing red or purple dots in the skin.
- Back pain, pain in joints and muscles.
- Cough
- Nausea

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CANURETIC.

5. How to store CANURETIC

Store all medicines out of reach of children.

Store at or below 25 °C.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton, bottle and/or the blister strip after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CANURETIC contains

The active substances are candesartan cilexetil and hydrochlorothiazide.

Austell Pharmaceuticals (Pty) Ltd, 49/7.1.3/0054, CANURETIC, 16/12,5 mg, Tablets

Each CANURETIC tablet contains 16 mg candesartan cilexetil and 12,5 mg hydrochlorothiazide.

The other ingredients are docusate sodium, sodium lauryl sulphate, carmellose calcium, pre-gelatinized maize starch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate (E572).

What CANURETIC looks like and contents of the pack

CANURETIC are packed in transparent PVC / PVDC aluminium blister packages of 28 or 30 tablets in an outer carton.

CANURETIC tablets are white, elliptic biconvex tablets, marked **CH** and **16** on the same face; and are scored on both faces.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Not all pack sizes may be marketed.

Holder of certificate of registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

This leaflet was last revised in

02 February 2023

Registration number

49/7.1.3/0054

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835