PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

Candepres® Plus 16/12,5 mg (tablets)

Candesartan cilexetil and Hydrochlorothiazide

Contains sugar (75,850 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking CANDEPRES PLUS 16/12,5

- 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.
- **CANDEPRES PLUS 16/12,5** 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.

What is in this leaflet

1. What **CANDEPRES PLUS 16/12,5** is and what it is used for
2. What you need to know before you take **CANDEPRES PLUS 16/12,5**
3. How to take **CANDEPRES PLUS 16/12,5**
4. Possible side effects
5. How to store **CANDEPRES PLUS 16/12,5**
6. Contents of the pack and other information

1. What CANDEPRES PLUS 16/12,5 is and what it is used for

CANDEPRES PLUS 16/12,5 belongs to a group of medicines known as angiotensin II receptor antagonists. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them. Hydrochlorothiazide belongs to a group of medicines called diuretics

(water tablets). Its effects promote the urinary extraction of sodium chloride and water which results in a lowering of the blood pressure.

CANDEPRES PLUS 16/12,5 is indicated for essential hypertension (high blood pressure) in patients stabilised on the individual components given at the same dosages.

2. What you need to know before you take CANDEPRES PLUS 16/12,5

Do not take CANDEPRES PLUS 16/12,5, if you:

- Are hypersensitive (allergic) to candesartan cilexetil, hydrochlorothiazide or any of the ingredients of **CANDEPRES PLUS 16/12,5** (listed in section 6).
- Have a history of angioedema (an acute condition characterized by the sudden development of localized, swollen, itchy lesions on the skin) related to previous ACE-inhibitor therapy (e.g. enalapril) or angiotensin receptor blockers (e.g. losartan, valsartan).
- Have a heart disorder.
- Have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- Have severe kidney disease.
- Have a kidney disease called renal artery stenosis (the narrowing of blood arteries in the kidneys) if you only have one working kidney.
- Are using potassium sparing diuretic medicines (water tablets) to control your blood pressure, such as spironolactone, triamterene, amiloride.
- Have porphyria.
- Have Addison’s disease (adrenal glands not working properly, which may cause weakness, tiredness, weight loss and low blood pressure).
- Are on lithium therapy (mood stabiliser).
- **CANDEPRES PLUS 16/12,5** should not be given to children.
- Are pregnant or breastfeeding your baby.

- Are using aliskiren-containing products used to treat high blood pressure.
- Have refractory lowered blood levels of potassium (hypokalaemia) and elevated blood levels of calcium (hypercalcaemia).
- Have gout (a condition where too much uric acid in the body causes joint pains).

If you think any of the above conditions applies to you, consult your doctor or pharmacist immediately.

Warnings and precautions

Before you take **CANDEPRES PLUS 16/12,5** tell your doctor or health care provider if you:

- Are taking other blood pressure lowering medicine (see Other medicines and **CANDEPRES PLUS 16/12,5**).
- Have or had systemic lupus erythematosus (a chronic inflammatory disease that can affect various parts of the body, especially the skin, joints, blood, and kidneys).
- Have heart, liver or kidney problems.
- Have asthma, allergy or experience allergic reaction.
- Had a kidney transplant recently.
- Need an operation, since combination of **CANDEPRES PLUS 16/12,5** may cause a drop in blood pressure when combined with some anaesthetics.
- Have problems with the valves of your heart.
- Have a disease of adrenal gland (Conn's disease – hyperaldosteronism).
- Have an electrolyte imbalance.
- Experience higher calcium level or gallbladder problems.
- Have Addison's disease (adrenal glands not working properly, which may cause weakness, tiredness, weight loss and low blood pressure).
- Taking potassium supplements, heparin, trimethoprim or sulfamethoxazole.
- Are taking medicines used to treat diabetes.

- If you experience symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- Have had skin cancer or if you develop an unexpected skin lesion (an abnormal growth or skin appearance) 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 **CANDEPRES PLUS 16/12,5**.
- Experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking **CANDEPRES PLUS 16/12,5**. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.
- 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 **CANDEPRES PLUS 16/12,5**, seek medical attention immediately.

Children and adolescents

There is no experience with the use of **CANDEPRES PLUS 16/12,5** in children (below the age of 18 years). Therefore, **CANDEPRES PLUS 16/12,5** should not be given to children.

Other medicines and CANDEPRES PLUS 16/12,5

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

Please consult your doctor, pharmacist or health care provider for advice. In particular, tell your doctor if you are taking/received any of the following medicines:

- Other medicines to help lower your blood pressure, including ACE inhibitors (enalapril, captopril, lisinopril or ramipril) and angiotensin receptor blockers (e.g. losartan, valsartan).

- Aliskiren medicines - used to treat high blood pressure.
- Water tablets (diuretics), e.g. furosemide.
- Warfarin - used to treat blood clots.
- Digoxin or nifedipine - used to treat heart diseases.
- Oral contraceptives (ethinylestradiol/levonorgestrel) - used to prevent pregnancy.
- Glibenclamide - used to treat diabetes.
- Laxatives (medicines used to treat constipation).
- Amphotericin B (medicine for treating fungal infections).
- Carbenoxolone (medicine for treating peptic ulcer and gastro-oesophageal reflux disease).
- Penicillin G sodium (medicine for treating infections).
- Potassium supplements or salt substitutes containing potassium.
- Heparin (blood thinning medication).
- Antiarrhythmics such as quinidine, hydroquinidine, disopyramide or amiodarone, sotalol, dofetilide, ibutilide (medicines to regulate heart rhythm).
- Lithium (medicine used for the treatment of mania or depression).
- Medicines such as ibuprofen, naproxen or diclofenac that are known as non-steroidal anti-inflammatory drugs (NSAIDs) – used for the treatment of pain and inflammation.
- Medicines such as celecoxib or etoricoxib that are known as COX-2 inhibitors.
- Salicylic acid derivatives, acetylsalicylic acid (aspirin), if you are taking more than 3 g each day.
- Antipsychotics such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopride, amisulpride, tiapride, pimozide, haloperidol, droperidol - used to treat schizophrenia and bipolar disorder.
- Bepridil, vincamine or ketanserin - used to treat high blood pressure.
- Erythromycin or sparfloxacine - used to treat bacterial infections.
- Cisapride and diphemanil - used to treat stomach ulcers.
- Halofantrin - used to treat malaria.

- Mizolastin - used to treat allergies.
- Pentamidine - used to treat pneumonia.
- Terbinafine - used to treat fungal infections.
- Colestipol or cholestyramine (resin-type lipid-lowering medicines).
- Skeletal muscle relaxants (tubocurarine) – medicines for relaxing skeletal muscles.
- Calcium supplements or Vitamin D.
- Carvedilol, timolol, diazoxide, co-amilozide - used to treat high blood pressure.
- Anticholinergic medicines (atropine or biperiden - medicines for treating Parkinson disease).
- Amantadine (medicine for treating Parkinson's disease).
- Cytotoxic medicinal products (cyclophosphamide, methotrexate) - used for treating cancer.
- Steroids or adrenocorticotropic hormone (ACTH).
- Antidiabetic medicines, e.g. metformin and insulin (medicines for treating diabetes).
- Alcohol, barbiturates (sleeping pills) or anaesthetics (used to prevent pain during surgery).
- Carbamazepine used to treat epilepsy (fits).
- Trimethoprim used to treat bladder infections.
- Ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- Methyldopa used to treat hypertension.
- Probenecid, sulfinpyrazone or allopurinol (used in the treatment of gout).

Ask your doctor if you are not sure what these medicines are.

Not all interactions with **CANDEPRES PLUS 16/12,5** are included in this leaflet.

CANDEPRES PLUS 16/12,5 with food, drink and alcohol

CANDEPRES PLUS 16/12,5 may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Taking **CANDEPRES PLUS 16/12,5** during pregnancy may harm your baby and you need to consult your doctor as soon as possible if you find out that you are pregnant.

Women of childbearing age should ensure effective contraception.

It is not known if **CANDEPRES PLUS 16/12,5** is passed into a mother's breastmilk. Because of the potential for adverse effects, which can affect your baby, **CANDEPRES PLUS 16/12,5** should not be taken during breastfeeding. If you are taking **CANDEPRES PLUS 16/12,5** and are breastfeeding your baby, consult your doctor as soon as possible.

Driving and using machines

CANDEPRES PLUS 16/12,5 may make you feel tired or dizzy and hence impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **CANDEPRES PLUS 16/12,5** affects you.

CANDEPRES PLUS 16/12,5 contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **CANDEPRES PLUS 16/12,5**.

3. How to take CANDEPRES PLUS 16/12,5

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

Always take **CANDEPRES PLUS 16/12,5** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for **CANDEPRES PLUS 16/12,5** is 1 tablet once daily.
Most of the antihypertensive (blood pressure lowering) effect is usually attained within 4 weeks of starting treatment.

Use in the elderly

No initial dosage adjustment is necessary in elderly patients.

CANDEPRES PLUS 16/12,5 is not suitable for use in children (less than 18 years of age).

Take your tablet with a glass of water, preferably at the same time each day, with or without food.

If you have the impression that the effect of **CANDEPRES PLUS 16/12,5** is too strong or too weak, tell your doctor or pharmacist.

If you take more CANDEPRES PLUS 16/12,5 than you should

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

If you forget to take CANDEPRES PLUS 16/12,5

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

4. Possible side effects

CANDEPRES PLUS 16/12,5 can have side effects.

Not all side effects reported for **CANDEPRES PLUS 16/12,5** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CANDEPRES PLUS 16/12,5**, please consult your health care provider for advice.

If any of the following happens, stop taking CANDEPRES PLUS 16/12,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Low blood pressure (feeling like fainting).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CANDEPRES PLUS 16/12,5**. 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:

- Liver disease with nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine.
- Chest pain or heart attack.
- Changes in the way your heart beats, for example, if you notice it beating faster or slower.
- Necrotizing vasculitis is a condition that involves swelling of the blood vessel walls.
- Difficulty breathing, coughing, swelling, changes in skin colour (bluish/grey/pale), sweating or wheezing (signs of respiratory distress).
- Stomach pain, nausea and vomiting which are signs of pancreatitis (inflammation of the pancreas).
- Severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

- Severe skin disorder symptoms include butterfly rash on cheeks, large rash over arms, rash after exposure to sun, mouth ulcers and blisters, may affect organs.
- Kidney disease where you pass little or no urine. Other symptoms include drowsiness, nausea, vomiting and breathlessness.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection in the lungs (respiratory infection)
- Electrolyte imbalance, changes in the amount of calcium, sodium, potassium, magnesium, uric acid or blood glucose level (seen in tests)
- Low blood pressure (hypotension)
- Headache
- Light headedness
- Dizziness
- Vertigo
- Loss of appetite
- Vomiting
- Nausea
- Skin rash, hives, itching
- Glucose in urine
- Inability to get or maintain an erection
- Weakness
- An increase in cholesterol and triglyceride blood levels

Less frequent side effects:

- Changes in the number of blood cells which may present frequent infections such as fever, severe chills, sore throat or mouth ulcers (signs of blood cell problems)
- Sleep disturbances
- Depression
- Restlessness
- Feeling of pins and needles in the hands and feet
- Runny nose, nasal congestion, sneezing, sore throat, cough or nasal discharge
- Anorexia
- Stomach disturbances
- Diarrhoea
- Constipation
- Irregular liver function and liver enzymes
- Swelling mainly of the face and throat
- Hypochloraemic alkalosis (a condition wherein you have too low an intake of chloride or your body excretes too high levels of chloride)
- The worsening of diabetes
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- Back pain, temporary paralysis or weakness of muscles
- Joint pain
- Aching muscles, muscle tenderness or weakness, not caused by exercise or painful joints
- Vision disorder
- Decreased sexual ability

The frequency of the following side effects are unknown:

- Fatigue (feeling tired)
- Sore salivary glands

- Muscle spasms or gout (painful, swollen joints caused by uric acid crystals)
- Skin and lip cancer (Non-melanoma skin cancer)
- Blurred or yellow vision
- Sudden eye pain (acute angle-closure glaucoma)
- Fever

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, 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 **CANDEPRES PLUS 16/12,5**. Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store CANDEPRES PLUS 16/12,5

- Store at or below 25 °C.
- Store in the original package.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CANDEPRES PLUS 16/12,5 contains

Active ingredients:

Each **CANDEPRES PLUS 16/12,5** tablet contains 16 mg candesartan cilexetil and 12,5 mg hydrochlorothiazide.

Inactive ingredients:

Carrageenan

Corn Starch

Croscarmellose Sodium

Ferric Oxide Red (E172)

Ferric Oxide Yellow (E172)

Lactose Monohydrate

Magnesium Stearate

Povidone K30

What CANDEPRES PLUS 16/12,5 looks like and contents of the pack

CANDEPRES PLUS 16/12,5 are apricot, mottled, oval biconvex tablets, scored on both sides.

CANDEPRES PLUS 16/12,5 tablets are packed as 30 tablets in:

Aluminium/aluminium blisters (hard foil: silver aluminium foil, coated with a polyester lacquer (matte outer side), polyurethane primer and LDPE layer (glossy inner side) and soft foil: silver (outer)/blue (inner) aluminium foil, with a desiccant, coated with oriented polyamide (matte outer side), LDPE layer with a desiccant and HDPE layer (blue inner side)). Each blister strip contains ten tablets with three blister strips packed into a cardboard carton.

or

White, round, high density polyethylene (HDPE) bottles closed with white, round, polypropylene (PP) cap - child resistant closure (CRC), fitted with an induction heat seal liner.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

V4.0 (29/08/2022)

Waterfall City

Jukskei View

Midrand

2090

Marketed by: Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets, Woodstock, Cape Town, 8001

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07