

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using CIPLASYL PLUS 4 TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- CIPLASYL PLUS 4 TABLETS 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.

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CIPLASYL PLUS 4 TABLETS (tablet)

1. WHAT CIPLASYL PLUS 4 TABLETS CONTAIN

Active ingredients:

Each tablet contains 4 mg perindopril tert-butylamine and 1,25 mg indapamide.

Inactive ingredients:

Lactose, sodium hydrogen carbonate, colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose.

Contains sugar: 62,3 mg lactose per tablet.

2. WHAT CIPLASYL PLUS 4 TABLETS ARE USED FOR

CIPLASYL PLUS 4 TABLETS are used to treat high blood pressure.

If high blood pressure is not treated it may lead to serious health problems, such as stroke, heart disease and kidney failure. CIPLASYL PLUS 4 TABLETS helps to lower your blood pressure.

3. BEFORE YOU TAKE CIPLASYL PLUS 4 TABLETS

Do not take CIPLASYL PLUS 4 TABLETS:

- If you are allergic (hypersensitive) to perindopril, indapamide, sulphonamides or any of the other ingredients (see WHAT CIPLASYL PLUS 4 TABLETS CONTAIN).
- If you have experienced serious swelling of the face, tongue, lips or throat either suddenly or in response to another medicine in the past (a rare allergic condition known as angioedema). You should also not take CIPLASYL PLUS 4 TABLETS if you have a family history of angioedema.
- If you have a heart disease.
- If you have a kidney disorder or suffer from renal artery stenosis (a problem with the blood vessels to one or both kidneys).
- If you suffer from aortic stenosis (when the heart's aortic valve closes up).
- If you are using potassium-sparing diuretics (water pills) such as spironolactone, triamterene or amiloride.
- If you have porphyria.
- If you are taking lithium – a medicine sometimes used for depression (see Using other medicines with CIPLASYL PLUS 4 TABLETS).
- If you have a serious liver disorder.
- If you have high levels of potassium, and/or are taking potassium supplements.
- If you are pregnant, trying to become pregnant or are breastfeeding (see Pregnancy and breastfeeding).

Take special care with CIPLASYL PLUS 4 TABLETS:

- Consult your doctor immediately if you are pregnant or trying to become pregnant.
- If you have a heart disease.
- If you have high or low levels of potassium, sodium or other problems with salt balance.
- If you have systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).
- If you have a kidney disease.
- If you have a liver disease.
- If you have diabetes (high blood sugar).
- If you have gout.

Taking CIPLASYL PLUS 4 TABLETS with food or drink:

CIPLASYL PLUS 4 TABLETS must preferably be taken in the morning before a meal.

Pregnancy and breastfeeding:

DO NOT take CIPLASYL PLUS 4 TABLETS if you are pregnant or suspect that you are pregnant. CIPLASYL PLUS 4 TABLETS may harm your unborn baby. Contact your doctor immediately.

DO NOT take CIPLASYL PLUS 4 TABLETS if you are breastfeeding your baby.

Driving and using machinery:

CIPLASYL PLUS 4 TABLETS may 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 CIPLASYL PLUS 4 TABLETS affects you.

Important information about some of the ingredients of CIPLASYL PLUS 4 TABLETS:

CIPLASYL PLUS 4 TABLETS contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking CIPLASYL PLUS 4 TABLETS.

Using other medicines with CIPLASYL PLUS 4 TABLETS:

Consult your doctor, pharmacist or healthcare professional for advice if you need to take any other medicines.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CIPLASYL PLUS 4 TABLETS with these medicines may cause undesirable interactions.

Not all interactions that may occur are included in this leaflet.

Do not take the following medicines in combination with CIPLASYL PLUS 4 TABLETS:

- Diuretics (also called water tablets, used in the treatment of high blood pressure).
 - Some medications used to treat high blood pressure, a fast or irregular heartbeat and other heart conditions.
 - Steroid medicines (such as corticosteroids, used for inflammation or allergies).
 - Anticoagulants (used to prevent the forming of blood clots).
 - Medicines used to treat diabetes (metformin tablets or insulin).
 - Baclofen (a muscle relaxer and an antispasmodic agent).
 - Anti-inflammatory medicines (such as NSAIDs, used to treat inflammation and pain).
 - Tricyclic antidepressants (such as imipramine, used to treat depression).
- (See Do not take CIPLASYL PLUS 4 TABLETS).

4. HOW TO TAKE CIPLASYL PLUS 4 TABLETS

The recommended dosage is one tablet per day as a single dose, preferably to be taken in the morning, before a meal.

Your doctor will advise you on the duration of your CIPLASYL PLUS 4 TABLETS treatment.

If you have a kidney disorder:

If you have a kidney disorder, please consult your doctor before taking CIPLASYL PLUS 4 TABLETS.

If you take more CIPLASYL PLUS 4 TABLETS than you should:

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your CIPLASYL PLUS 4 TABLETS:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up the missed dose.

5. POSSIBLE SIDE EFFECTS

CIPLASYL PLUS 4 TABLETS may have side effects. Not all side effects reported for CIPLASYL PLUS 4 TABLETS are included in this leaflet.

Should your general health worsen while taking CIPLASYL PLUS 4 TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop using CIPLASYL PLUS 4 TABLETS and seek emergency help if you have any of these signs of an allergic reaction:

- hives; difficulty breathing; swelling of your face, lips, tongue or throat
- jaundice (pain across your liver, yellowing of eyes and skin, severe nausea)
- Stevens-Johnson syndrome (facial and tongue swelling, red or purple skin rash, blisters on skin/shedding of skin).

Consult your doctor if any of the following side effects continue or are bothersome:

- headache
- dry cough
- feeling tired or as if you have less energy
- feeling faint, light-headed or dizzy
- feeling sick (nausea) or having stomach pain
- diarrhoea, taste disturbances
- muscle pain and cramps
- an increased risk of becoming dehydrated (dry, sticky mouth; sleepiness, thirst, dry skin, headache, constipation and dizziness) (in elderly patients and in patients with heart failure)
- chest pain
- skin rash
- fever
- loss of appetite
- yellow vision
- sinusitis (inflammation of the sinus)
- tightness in your chest – difficulty breathing.

6. STORAGE AND DISPOSAL OF CIPLASYL PLUS 4 TABLETS

- Store at or below 25 °C in a dry place.
- Do not remove from outer carton until required for use.
- KEEP 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 of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF CIPLASYL PLUS 4 TABLETS

CIPLASYL PLUS 4 TABLETS are packed into either:

- Transparent PVC/PVDC aluminium blister strips containing 10 tablets. Three blisters (3 x 10) are packed into a laminated aluminium pouch.
- Alu/Alu blister strip containing 10 tablets. Three blisters (3 x 10) are packed into a cardboard carton.

8. IDENTIFICATION OF CIPLASYL PLUS 4 TABLETS

White to off-white, oblong shaped, flat faced, bevelled edge tablet with a median line on both sides.

9. REGISTRATION NUMBER

44/7.1.3/0503

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Zydus Healthcare SA (Pty) Ltd
Southdowns Office Park
Building B, Ground Floor
22 Karee Street
Centurion, Pretoria
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11. DATE OF PUBLICATION

02 March 2012