

PATIENT INFORMATION LEAFLET

CIPALAT XR

SCHEDULING STATUS S3

CIPALAT XR 30 extended release tablets

CIPALAT XR 60 extended release tablets

Nifedipine

Sugar free

Read all of this leaflet carefully before you start taking CIPALAT XR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider
- CIPALAT XR 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 CIPALAT XR is **and** what it is used for
2. What you need to know before **you** take CIPALAT XR
3. How to take CIPALAT XR
4. Possible side effects
5. How to store CIPALAT XR
6. Contents of the pack and other information.

1. WHAT CIPALAT XR is and what it is used for

CIPALAT XR contains nifedipine which belongs to a group of medicines called calcium-channel blockers that act on the cardiovascular system (the heart and blood vessels).

CIPALAT XR has been prescribed by your doctor to treat your mild to moderate high blood pressure or to reduce the frequency of your chronic stable anginal attacks (chest pains).

2. What you need to know before you take CIPALAT XR

Do not take CIPALAT XR if

- You are allergic to nifedipine any other similar medicines (known as dihydropyridines) or any of the other ingredients in CIPALAT XR listed in **section 6**. (An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet or breathing difficulties).
- You have been told that you have a narrowing (stenosis) of the aortic valve in your heart.
- You have experienced a collapse which was caused by a heart problem (cardiogenic shock).
- The severity or frequency of your angina has rapidly worsened over a matter of hours or days (unstable angina).
- You suffer from inflammation of the bowel or intestines (such as Crohn's disease), oesophageal (gullet) obstruction or have in the past had an obstruction or narrowing of the intestine.
- You have a liver disease.

- You have had a heart attack during the last month or were treated for a heart attack.
- You are taking the antibiotic rifampicin (used to treat tuberculosis).
- Your blood pressure continues to rise despite treatment (malignant hypertension).
- You have a Kock pouch (a type of ileostomy).
- You are pregnant or if you are breastfeeding.

Warnings and precautions

Take special care with CIPALAT XR

Consult your doctor before you start taking CIPALAT XR if:

- You suffer from low blood pressure.
- You are diabetic, the treatment for your diabetes may need to be adjusted
- You are receiving kidney dialysis and have very high blood pressure and kidney failure associated with low blood volume.
- You are taking other medicines to treat high blood pressure (e.g. beta-blockers). If you are changing from a beta-blocker to CIPALAT XR, your doctor may reduce your beta-blocker after discussion with your doctor.
- You have to give a urine sample, have a barium contrast x-ray or undergo surgery.
- You are male and have been unsuccessful in fathering a child by in vitro fertilisation. CIPALAT XR have been shown to impair sperm function.
- Upon swallowing the tablet, CIPALAT XR allows a slow release of the therapeutic substance in the body which guarantees an action over 24 hours, and the tablet remains are eliminated in the patient's stools (faeces) as an insoluble shell appearing

to be the complete tablet, however it should be noted this is completely normal and is due to the technical characteristics of CIPALAT XR tablets.

Your doctor may, under certain conditions, think it necessary to keep you on CIPALAT XR whilst you are pregnant. If this is the case particular care must be taken if you are also having magnesium sulphate injections (may cause a severe fall in blood pressure).

Taking CIPALAT XR with food and drink

Do not drink grapefruit juice at the same time or soon after taking CIPALAT XR because grapefruit juice can increase the blood levels of CIPALAT XR.

Pregnancy, breastfeeding and fertility

Do not take CIPALAT XR if you are pregnant or breastfeeding. Do not take CIPALAT XR if you are breastfeeding. If you need to take CIPALAT XR, you should stop breastfeeding before you start taking this medicine.

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 healthcare provider for advice before you take CIPALAT XR.

If you are a man who has been unable to father a child by in vitro fertilisation, medicines like CIPALAT XR have been shown to impair sperm function.

Driving and using machines

CIPALAT XR may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way.

This may be more likely when you first start treatment, if you change medicine, or if you have ingested alcohol.

Other medicines and CIPALAT XR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

- other medicines to treat high blood pressure
- cimetidine, to treat stomach ulcers
- digoxin, diltiazem, quinidine, or beta-blockers, used to treat heart conditions
- the anti-epileptic medicine phenytoin
- the antibiotic rifampicin
- combination treatment quinupristin/dalfopristin
- cisapride, a medicine used to speed up the movement of food through the gullet and stomach.

The effect of the following medicines on CIPALAT XR is uncertain. Therefore, as an additional precaution, please tell your doctor if you are taking:

- the antibiotics erythromycin, ketoconazole, itraconazole or fluconazole
- indinavir, nelfinavir, ritonavir or saquinavir, used to treat HIV infection
- the antidepressant medicines fluoxetine and nefazodone
- tacrolimus, an immunosuppressant used to prevent the rejection of transplant organs
- carbamazepine and valproic acid, used for the treatment of epilepsy
- the barbiturate phenobarbitone, used primarily to treat insomnia and anxiety

Sodium content

CIPALAT XR contains less than 1 mmol sodium (23 mg) per tablet, that is to say 'sodium-free'.

3. How to take CIPALAT XR

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

Always take CIPALAT XR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

CIPALAT XR is formulated so that you only have to take your tablets **once a day**. It is important that you take your tablets **at the same time each day**, preferably in the morning. Your tablet must be swallowed whole with a glass of water and **not** with grapefruit juice. **Do not break or chew your tablets.**

Adults:

The usual adult dose for treating high blood pressure or preventing angina is 30 mg or 60 mg once a day. Your doctor may decide to increase your dose to a maximum of 90 mg of CIPALAT XR once a day.

If you are elderly, lower doses of CIPALAT XR may be prescribed by your doctor.

Children:

CIPALAT XR is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

If you take more CIPALAT XR than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

Taking too many tablets may cause your blood pressure to become too low and your heartbeat to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take CIPALAT XR

If you forget to take a dose, do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CIPALAT XR

Do **not** stop taking your medicine until your doctor tells you.

If you have any further questions on the use of CIPALAT XR, ask your doctor, nurse, or pharmacist.

4. Possible side effects

CIPALAT XR can have side effects.

Not all side effects reported for CIPALAT XR are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking CIPALAT XR, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking CIPALAT XR 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, rash or itching.

These are all serious side effects and you may have had an allergic reaction to CIPALAT XR. You may need urgent medical care or hospitalisation.

Tell your doctor if you notice any of the following other side effects that may occur:

Frequent side effects

- Headache
- Swelling
- Constipation
- Feeling unwell
- Pain in eye.

Less frequent side effects

- Anxiety reactions, sleep disorders
- Vertigo, migraine, dizziness, tremor
- Visual disturbance
- Palpitations (irregular heartbeat)
- Nosebleed, nasal congestion, shortness of breath

- Abdominal pain, dry mouth, indigestion, flatulence, vomiting, nausea (feeling sick), sore gums, intestinal obstruction, intestinal ulcer
- Skin rash, itching
- Muscle cramps, joint swelling
- Erectile dysfunction
- Unspecified pain, chills
- Trembling, abnormal sensation (dysesthesia)
- Drowsiness (somnolence)
- Chest pain (angina)
- Fall in blood pressure
- Fainting (syncope)
- Heartburn or indigestion (gastroesophageal sphincter insufficiency)
- Temporary increase in certain liver enzymes
- Increase in the need to pass water
- Painful or difficult urination.

Side effects with frequency unknown

- a more severe decrease in a specific class of white blood cell (agranulocytosis)
- a reduction in the number of white blood cells (leucopenia)
- sudden generalised allergic reaction including very rarely life-threatening shock
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hypoesthesia)
- difficulty in breathing

- swelling in lungs
- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal
- difficulty swallowing
- abdominal pain, caused by obstruction of the gut or ulcers in the gut
- vomiting
- sensitivity to light (photosensitivity allergic reaction)
- enlargement of a man's breasts (gynaecomastia).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA **website**, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By **reporting** side effects, you can help provide more information on the safety of CIPALAT XR.

5. How to store CIPALAT XR

Store at or below 25 °C.

Do not remove the blisters from the cartons until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

Do not use CIPALAT XR after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

Ask your pharmacist how to dispose of medicines no longer required.

6. Contents of the pack and other information

What CIPALAT XR contains

The active substance in CIPALAT XR is nifedipine. Each CIPALAT XR 30 tablet contains 30 mg nifedipine and each CIPALAT XR 60 tablet contains 60 mg nifedipine.

The inactive ingredients are cellulose acetate, ferric oxide, hydroxyl propyl methyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, sodium chloride, talc and titanium dioxide.

What CIPALAT XR looks like and contents of the pack CIPALAT XR 30

Tablets are packed in plain aluminium and clear PVC/PE/PVdc blisters containing 14 or 15 tablets per blister in carton.

Pack size: 28's, 30's

Not all pack sizes are necessarily marketed.

CIPALAT XR 60

Tablets are packed in plain aluminium and clear PVC/PE/PVDC blisters containing 14 or 15 tablets per blister placed in a carton

Pack size: 28's, 30's

Not all pack sizes are necessarily marketed.

CIPALAT XR 30

Pink coloured, film-coated circular biconvex tablet having an orifice on one side and plain on the other.

CIPALAT XR 60

Pink coloured, film-coated circular biconvex tablet having an orifice on one side and plain on the other.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Access to the corresponding Professional Information and translated professional patient information leaflet:

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to
be generated and
included after
approval.