

Module 1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NIFEDIPINE CIPLA XR 30 Controlled release tablets

NIFEDIPINE CIPLA XR 60 Controlled release tablets

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **NIFEDIPINE CIPLA 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 NIFEDIPINE CIPLA XR CONTAINS

The active substance in **NIFEDIPINE CIPLA XR** is nifedipine. Each **NIFEDIPINE CIPLA XR 30** tablet contains 30 mg nifedipine and each **NIFEDIPINE CIPLA 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.

NIFEDIPINE CIPLA XR is sugar free.

WHAT NIFEDIPINE CIPLA XR IS USED FOR:

NIFEDIPINE CIPLA 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).

NIFEDIPINE CIPLA 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).

BEFORE YOU TAKE NIFEDIPINE CIPLA XR

Do not take NIFEDIPINE CIPLA XR if:

- You are allergic to nifedipine or any of the inactive ingredients in **NIFEDIPINE CIPLA XR**. (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.

Take special care with NIFEDIPINE CIPLA XR

Consult your doctor before you start taking **NIFEDIPINE CIPLA 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 **NIFEDIPINE CIPLA 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. **NIFEDIPINE CIPLA XR** have been shown to impair sperm function.

Your doctor may, under certain conditions, think it necessary to keep you on **NIFEDIPINE CIPLA XR** whilst you are pregnant. If this is the case particular care must be taken if you are also having magnesium sulphate injections.

Taking NIFEDIPINE CIPLA XR with food and drink

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

Pregnancy and breastfeeding

Do not take **NIFEDIPINE CIPLA XR** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before you take **NIFEDIPINE CIPLA XR**.

Driving and using machinery

You should take care while driving or using machinery until you know how **NIFEDIPINE CIPLA XR** affects you.

Taking other medicines with NIFEDIPINE CIPLA 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 **NIFEDIPINE CIPLA 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

HOW TO TAKE NIFEDIPINE CIPLA XR

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

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

NIFEDIPINE CIPLA 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 **NIFEDIPINE CIPLA XR** once a day.

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

Children:

NIFEDIPINE CIPLA 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 NIFEDIPINE CIPLA XR than you should:

In the event of overdosage, 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.

If you forget to take NIFEDIPINE CIPLA 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.

Effects when treatment with NIFEDIPINE CIPLA XR is stopped:

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

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

POSSIBLE SIDE EFFECTS

NIFEDIPINE CIPLA XR can have side effects.

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

If any of the following serious side effects occur, stop taking NIFEDIPINE CIPLA 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 serious side effects and you may have had an allergic reaction to **NIFEDIPINE CIPLA 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

Less frequent side effects:

- Anxiety reactions, sleep disorders
- Vertigo, migraine, dizziness, tremor
- Visual disturbance
- Palpitations
- Nosebleed, nasal congestion, shortness of breath
- Abdominal pain, dry mouth, indigestion, flatulence, vomiting, nausea, sore gums, intestinal obstruction, intestinal ulcer
- Skin rash, itching
- Muscle cramps, joint swelling
- Erectile dysfunction
- Unspecified pain, chills

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORAGE AND DISPOSAL INFORMATION

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 **NIFEDIPINE CIPLA 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.

PRESENTATION OF NIFEDIPINE CIPLA XR

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

Pack size: 28's

IDENTIFICATION OF NIFEDIPINE CIPLA XR

NIFEDIPINE CIPLA XR 30

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

NIFEDIPINE CIPLA XR 60

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

REGISTRATION NUMBERS

NIFEDIPINE CIPLA XR 30: 50/7.1/0619

NIFEDIPINE CIPLA XR 60: 50/7.1/0620

NAME AND ADDRESS OF THE REGISTRATION HOLDER

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RSA

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