

# APO-NIFEDIPINE XR

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using APO-NIFEDIPINE XR?

APO-NIFEDIPINE XR contains the active ingredient *nifedipine*. APO-NIFEDIPINE XR is used to treat hypertension (high blood pressure) or to prevent chronic stable angina, a type of angina.

For more information, see Section [1. Why am I using APO-NIFEDIPINE XR?](#) in the full CMI.

### 2. What should I know before I use APO-NIFEDIPINE XR?

Do not use if you have ever had an allergic reaction to nifedipine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use APO-NIFEDIPINE XR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-NIFEDIPINE XR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use APO-NIFEDIPINE XR?

The usual starting dose is 30mg (one 30mg tablet) daily.

More instructions can be found in Section [4. How do I use APO-NIFEDIPINE XR?](#) in the full CMI.

### 5. What should I know while using APO-NIFEDIPINE XR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using APO-NIFEDIPINE XR.</li><li>• If you are about to be started on any new medication, tell your doctor that you are taking APO-NIFEDIPINE XR.</li><li>• Tell your doctor you are pregnant or planning to become pregnant.</li><li>• Tell your doctor you are breast-feeding or are planning to breast-feed.</li><li>• Tell your doctor you are about to have any blood or urine tests, or a Barium Contrast X ray.</li><li>• Tell your doctor you are going to have surgery or an anesthetic or are going into hospital.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly, or change the dosage, without first checking with your doctor.</li><li>• Do not take this medicine to treat any other condition unless your doctor or pharmacist tells you to.</li><li>• Do not give this medicine to anyone, even if their symptoms seem similar to yours.</li><li>• You should not eat grapefruit or drink grapefruit juice while you are taking nifedipine or for 3 days before starting to take nifedipine.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful when driving or operating machinery until you know how this medicine affects you.</li><li>• Nifedipine may cause dizziness, light-headedness or fainting in some patients. If affected, do not drive a vehicle or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Your doctor may advise you to limit your alcohol intake.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in a cool dry place where the temperature will stay below 25°C.</li><li>• Keep your medicine in its original packaging until it is time to take it.</li></ul>

For more information, see Section [5. What should I know while using APO-NIFEDIPINE XR?](#) in the full CMI.

### 6. Are there any side effects?

Common and mostly mild side effects include headache, feeling dizzy, fast or irregular heartbeats, constipation, general swelling and/or swelling of arms, ankles or legs, generally feeling unwell or in pain and jaundice. Refer to the CMI for all side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# APO-NIFEDIPINE XR

Active ingredient: *nifedipine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-NIFEDIPINE XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-NIFEDIPINE XR.**

Where to find information in this leaflet:

- [1. Why am I using APO-NIFEDIPINE XR?](#)
- [2. What should I know before I use APO-NIFEDIPINE XR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-NIFEDIPINE XR?](#)
- [5. What should I know while using APO-NIFEDIPINE XR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using APO-NIFEDIPINE XR?

**APO-NIFEDIPINE XR contains the active ingredient nifedipine.** Nifedipine belongs to a group of medicines called calcium channel blockers. They work by relaxing and opening up the blood vessels in the body to lower blood pressure and to improve the supply of blood and oxygen to the heart.

**APO-NIFEDIPINE XR is used to treat hypertension (high blood pressure) or to prevent chronic stable angina, a type of angina.**

APO-Nifedipine XR is designed to allow the slow release of the nifedipine from the tablet after it is taken.

There is no evidence that this medicine is addictive.

## 2. What should I know before I use APO-NIFEDIPINE XR?

### Warnings

**Do not use APO-NIFEDIPINE XR if you have had the following:**

- a heart attack in the last 8 days
- cardiogenic shock (very low blood pressure due to a failing heart)
- a Kock Pouch (an ileostomy)
- the rare inherited problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption. These tablets contain lactose
- you are taking another medicine called rifampicin, an antibiotic

- have had an allergic reaction to nifedipine, similar medicines such as amlodipine, felodipine, lercanidipine, nimodipine and isradipine or any of the ingredients listed at the end of this leaflet.

### Check with your doctor if you:

- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have any medical conditions, especially the following:
  - heart problems such as heart failure, angina or narrowing of any of the blood vessels going into or out of the heart
  - other heart or blood vessel disorders
  - low blood pressure
  - stroke
  - mini-stroke (also known as TIA transient ischaemic attack)
  - diabetes
  - liver problems
  - kidney disease or having dialysis
  - narrowing of your oesophagus or intestine, e.g. due to previous injury, infection or surgery
  - prolonged diarrhoea or other bowel problems, e.g. Crohn's Disease or Ulcerative Colitis
  - surgery on your bowel
- You are currently pregnant or breast-feeding or you plan to become pregnant or breast-feed. Your doctor will discuss alternative medicines with you, as you must not take nifedipine whilst pregnant or breast feeding.
- You are planning to have surgery or an anaesthetic or are going into hospital.
- You are currently receiving or are planning to receive dental treatment.
- You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

You should not eat grapefruit or drink grapefruit juice while you are taking nifedipine or for 3 days before starting to take nifedipine, because this may cause your blood pressure to drop too low.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Nifedipine may affect your developing baby if you take it during pregnancy.

Nifedipine may pass into human breast milk.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with APO-NIFEDIPINE XR and affect how it works. These include:**

- Beta blockers, e.g. metoprolol, atenolol
- other medicines used to treat high blood pressure or angina, e.g. diltiazem
- medicines used to treat arrhythmia (fast or irregular heartbeats), e.g. quinidine
- other medicines used to treat heart disease, e.g. digoxin
- some medicines used to treat stomach ulcers and heartburn, e.g. cimetidine, cisapride
- rifampicin, used to treat tuberculosis and other serious infections
- other medicines used to treat bacterial infections, e.g. erythromycin, quinupristin, dalfopristin
- medicines used to treat fungal infections, e.g. ketoconazole
- medicines used to treat HIV, e.g. ritonavir
- medicines used to treat epilepsy, e.g. phenytoin, carbamazepine, valproic acid, phenobarbitone
- anti-depressants, e.g. fluoxetine, nefazodone
- tacrolimus, used to prevent rejection after organ transplant. Tacrolimus is a medicine used after organ transplant.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with nifedipine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-NIFEDIPINE XR.**

### 4. How do I use APO-Nifedipine XR?

#### How much to take / use

- Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.
- Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- The usual starting dose is 30 mg (one 30 mg tablet) daily.
- Your doctor may increase the dose slowly over several weeks depending on how you respond to this medicine. If you are being treated for high blood pressure the maximum dose is 120 mg, and if you have chronic angina, the maximum dose is 90 mg.

- If a dose less than 30 mg is needed you will have to take a different brand of nifedipine.
- If you have liver problems or are taking certain other medicines or you are elderly or of South Asian origin, your doctor may prescribe a lower dose.
- Children under 18 years of age must not take this medicine.
- Do not stop taking your medicine suddenly or change your dosage without first checking with your doctor.
- Follow the instructions provided and use APO-NIFEDIPINE XR until your doctor tells you to stop.

#### When to take APO-NIFEDIPINE XR

- Take this medicine at the same time each day, usually in the morning.
- Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- It does not matter if you take it before, with or after food.

#### How to take APO-NIFEDIPINE XR

Swallow the tablets whole with a glass of liquid. Do not crush, chew or break up the tablets.

You should not eat grapefruit or drink grapefruit juice while you are taking Nifedipine or for 3 days before starting to take nifedipine, because this may cause your blood pressure to drop too low.

#### If you forget to use APO-NIFEDIPINE XR

APO-NIFEDIPINE XR should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, waiting 12 hours before taking your next dose.

**If it is almost time (within 12 hours) for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

#### If you use too much APO-NIFEDIPINE XR

If you think that you have used too much APO-NIFEDIPINE XR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

If you take too much nifedipine, you may feel dizzy or experience flushing and fainting due to a drop in blood pressure, irregular or fast or slow heart beats, fast or troubled breathing and even loss of consciousness.

## 5. What should I know while using APO-NIFEDIPINE XR?

### Things you should do

- Take the tablets exactly as you are told to by your doctor. If you do not follow your doctor's instruction you may not get control of your blood pressure or angina.
- Tell your doctor if you continue to have chest pain or angina attacks or if they become more frequent while you are taking APO-NIFEDIPINE XR.
- Tell your doctor that you are taking this medicine if:
  - you are about to be started on any new medicine.
  - you are pregnant or are planning to become pregnant.
  - you are breastfeeding or are planning to breast-feed.
  - you are about to have any blood or urine tests, or Barium Contrast X ray.
  - you are going to have surgery or an anesthetic or are going into hospital.
- If you are taking a beta blocker and your doctor has told you to stop taking it, make sure you gradually stop taking the beta blocker over few days.
- Your doctor may do tests to make sure the medicine is working and to prevent side effects, especially if you are taking other tablets as well or you have other medical conditions. Go to your doctor regularly for a check-up.
- Remind any doctor, dentist or pharmacist you visit that you are using APO-NIFEDIPINE XR.
- Get up slowly when getting out of bed or standing up. This is to avoid becoming light-headed, dizzy or faint. If you feel light-headed or dizzy, this may be because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from sleeping or sitting, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

### Call your doctor straight away if you:

- Are having an allergic reaction to APO-NIFEDIPINE XR. Do not take any more of this medicine and you're your doctor immediately or go the Accident and Emergency department at your nearest hospital. Symptoms of allergic reactions may include some or all of the following:
  - Cough, shortness of breath, wheezing or difficulty breathing
  - Swelling of the face, lips, tongue, or other parts of the body
  - Rash, itching or hives on the skin
  - Fainting
  - Hayfever-like symptoms

### Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Do not stop using this medicine suddenly, or change the dosage, without first checking with your doctor.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how this medicine affects you.

APO-NIFEDIPINE XR may cause dizziness, light-headedness or fainting in some people, especially when they start taking the medicine, when changing the dose in some cases when taking it with alcohol. If affected, do not drive a vehicle, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

Your doctor may advise you to limit your alcohol intake.

### Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging it may not keep well.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills. Heat and dampness can destroy some medicines.

#### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Headache</li><li>• Feeling dizzy</li><li>• Fast or irregular heartbeats</li><li>• constipation</li><li>• general swelling and/or swelling of arms, ankles or legs</li><li>• generally feeling unwell or in pain</li><li>• jaundice</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• fast, thumping or irregular heartbeat</li><li>• problems breathing</li><li>• rash, itching or hives on the skin.</li><li>• swelling of the face, lips, tongue, or other parts of the body</li><li>• signs of liver problems such as yellowing of the skin and/or eyes(jaundice)</li><li>• chest pain</li><li>• signs of frequent infections such as fever, severe chills, sore throat, or mouth ulcers</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What APO-Nifedipine XR contains

<b>Active ingredient (main ingredient)</b>	nifedipine
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• purified talc</li><li>• lactose monohydrate</li><li>• povidone</li><li>• carbomer 934P</li></ul>

	<ul style="list-style-type: none"><li>• hypromellose</li><li>• colloidal anhydrous silica</li><li>• magnesium stearate</li><li>• titanium dioxide</li><li>• iron oxide red CI77491</li><li>• macrogol 4000</li><li>• Eudragit E100.</li></ul>
<b>Potential allergens</b>	lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

**This medicine is gluten-free.**

### What APO-Nifedipine XR looks like

APO-NIFEDIPINE XR 30 mg tablets: Round, pale red tablet marked "30" on one side. (Aust R 152207).

APO-NIFEDIPINE XR 60 mg tablets: Round, pale red tablet marked "60" on one side. (Aust R 152208).

### Who distributes APO-Nifedipine XR

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121  
[www.arrotex.com.au](http://www.arrotex.com.au)

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