

APO-NIFEDIPINE XR

Contains the active ingredient, nifedipine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Nifedipine XR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Nifedipine XR. It contains the active ingredient, nifedipine. It is used to treat hypertension (high blood pressure) or to prevent chronic stable angina, a type of angina.

APO-Nifedipine XR is not used for the relief of a sudden attack of angina.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

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 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.

Use in children

There is not enough information to recommend using this medicine in children under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are or have had any of 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 used to treat various infections**
- **You are pregnant.**
Nifedipine may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding.**
Nifedipine may pass into human breast milk.
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**
- **You 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.**
Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had 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.
 - low blood pressure
 - diabetes
 - liver problems
 - kidney disease or having dialysis
 - blockage of your oesophagus or bowel
 - prolonged diarrhoea or other bowel problems, e.g. Crohn's Disease or Ulcerative Colitis
 - surgery on your bowel.
3. 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.
4. You are planning to have surgery or an anaesthetic or are going into hospital.
5. You are currently receiving or are planning to receive dental treatment.
6. 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.

Some medicines may interact with nifedipine. These include:

- Cimetidine or cisapride, used to treat stomach problems

- erythromycin, rifampicin or quinupristin and dalbopristin (Synercid), used to treat bacterial infections
- medicines used to treat virus infections, such as amprenavir, indinavir, nelfinavir, ritonavir or saquinavir
- medicines such as ketoconazole, itraconazole or fluconazole, used to treat fungal infections
- medicines such as warfarin, used to prevent blood clots
- medicines used to treat heart problems, angina or blood pressure, such as digoxin, diltiazem, glyceryl trinitrate or quinidine; or beta-blockers such as atenolol or metoprolol
- candesartan cilexetil or irbesartan, used for blood pressure, heart or kidney problems
- doxazosin, used for blood pressure or prostate problems
- certain medicines used to treat breathing problems, such as theophylline, terbutaline and salbutamol
- phenytoin, carbamazepine, phenobarbitone or sodium valproate, used to treat epilepsy
- tacrolimus, a medicine used after organ transplants
- nefazodone and fluoxetine, medicines used for depression
- other brands or types of nifedipine-containing medicines.

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 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.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

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.

How to take it

Swallow the tablets whole with a glass of liquid. Do not crush, chew or break up the tablets. Avoid drinking grapefruit juice whilst taking this medicine.

When to take it

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 long to take it for

APO-Nifedipine XR helps control your condition, but does not cure it. Therefore, you must take it every day.

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

Do not stop taking the tablets suddenly unless you are told to by your doctor.

If you forget to take it and it is almost time (within 12 hours) to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise (if more than 12 hours to the next dose), take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of unwanted side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

While you are taking this medicine

Things you must 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 breast-feeding or are planning to breast-feed

- you are about to have any blood or urine tests, or a Barium Contrast X ray
- you are going to have surgery or an anaesthetic 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 a 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.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine suddenly, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Nifedipine may cause dizziness, light-headedness or fainting in some patients, especially when they first start taking the medicine, when changing the dose or 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.

If you have been taking this medicine regularly for several weeks, do not suddenly stop using it.

Stopping suddenly may bring on your previous problem. Check with your doctor for the best way to reduce gradually the amount you are taking before stopping completely.

If you have angina, be careful not to overdo physical activities when you first start taking APO-Nifedipine XR.

You may feel better when you start taking it, but you will need time to improve your physical fitness.

Things that may help your condition

Some self-help measures suggested below may help your condition.

Talk to your doctor or pharmacist about them:

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Smoking - your doctor may advise you to stop smoking or at least cut down.
- Exercise - regular exercise helps reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is

fairly flat. Before starting any exercise, ask your doctor for the program that best suits you.

- Weight - if you are overweight, your doctor may suggest losing some weight to help lower your blood pressure and lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.
- Diet - eat a healthy low-fat diet that includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you can use minimum salt in cooking and avoid salt at the table.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-Nifedipine XR or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects.

Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- headache or migraine
- stuffy nose or nosebleed
- giddiness or light-headedness
- feeling or being sick
- diarrhoea or constipation
- wind or burping, heartburn or indigestion
- loss of appetite, weight loss
- dry mouth
- flushing, chills, sweating, fever
- eye pain
- unusual tiredness or weakness
- numbness or tingling in the hands and feet
- leg or muscle cramps or pain
- swollen or painful joints
- bleeding, tender or swollen or enlarged gums
- sleepiness, sleeplessness or problems sleeping
- feeling nervous or anxious
- lack of, or unusual, sensations
- unusual bruising
- itching, mild skin rash, skin problems or redness
- an increase in the amount of urine produced or the need to pass urine more often or the need to urinate at night time
- enlarged breasts
- generally feeling unwell or in pain
- sexual problems.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- feeling dizzy or faint when moving from lying or sitting down to standing up. This may happen when you first take these tablets or change the dose and may be a problem if it persists.
- swollen ankles, legs, face or body due to excess fluid
- pain or swelling in the stomach area

- redness and burning pain all over the body (mainly feet and hands)
- raised blood sugar levels (headache, feeling thirsty and tired, and passing large amounts of urine)
- shakiness
- sunburn-type rash following short exposure to the sun
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- problems seeing
- sore or swollen throat or problems swallowing
- red or purple blotches on the skin
- yellowing of the skin and/or whites of the eyes (jaundice)

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- fast, thumping or irregular heartbeat
- problems breathing
- chest pain or angina
- fainting
- skin which has become red, cracked, flaky or covered with scales or crusts
- any other serious skin rashes.

If you are a man who has had problems fathering a child by in vitro fertilisation, make sure your doctor knows you are taking nifedipine. In a small number of cases of in vitro fertilisation, medicines like nifedipine seemed to have interfered with normal sperm function. This effect went away after the medicine was stopped. Nifedipine should be considered as one of the possible causes if no other explanation can be found.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to APO- Nifedipine XR, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction 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

Storage and disposal

Storage

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.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO- Nifedipine XR looks like

APO-NIFEDIPINE XR 30 mg tablets: Round, pale red tablet marked "30" on one side.

APO-NIFEDIPINE XR 60 mg tablets: Round, pale red tablet marked "60" on one side.

Available in blister packs of 30 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 30 mg or 60 mg of nifedipine as the active ingredient.

It also contains the following inactive ingredients:

- purified talc
- lactose monohydrate
- povidone
- carbomer 934P
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- titanium dioxide
- iron oxide red C177491
- macrogol 4000
- Eudragit E100.

This medicine is gluten-free, sucrose-free, tartrazine-free and free from other azo dyes.

Australian Registration Numbers

APO-Nifedipine XR 30 mg Tablets
AUST R number 152207

APO-Nifedipine XR 60 mg Tablets
AUST R number 152208

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Distributor

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