

Consumer Medicine Information

ARROW - NIFEDIPINE XR

Nifedipine 30 and 60 mg extended release tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - NIFEDIPINE XR.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - NIFEDIPINE XR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What ARROW - NIFEDIPINE XR is used for

ARROW - NIFEDIPINE XR Tablets are used to treat high blood pressure or to prevent chronic stable angina (one of the different types of angina).

ARROW - NIFEDIPINE XR Tablets is not used for the relief of a sudden attack of angina.

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

ARROW - NIFEDIPINE XR is designed to allow the slow release of the active substance from the tablet after it is taken.

Your doctor may have prescribed ARROW - NIFEDIPINE XR for another reason. Ask your doctor if you have any questions about why ARROW - NIFEDIPINE XR has been prescribed for you.

There is no evidence that ARROW - NIFEDIPINE XR Tablets is addictive.

ARROW - NIFEDIPINE XR is available only with a doctor's prescription.

Before you take ARROW - NIFEDIPINE XR

When you must not take it

Do not take ARROW - NIFEDIPINE XR if you are allergic to medicines containing nifedipine, other calcium channel blockers such as amlodipine, felodipine and lercanidipine, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ("hives"), hayfever or fainting.

Do not take ARROW - NIFEDIPINE XR if you have or have had:

- heart attack in the last eight days
- cardiogenic shock (very low blood pressure due to a failing heart)
- Kock Pouch or ileostomy.

Do not take ARROW - NIFEDIPINE XR if you are taking another medicine containing the active substance rifampicin.

Do not take ARROW - NIFEDIPINE XR if you are pregnant.

ARROW - NIFEDIPINE XR may affect your developing baby if you take it during pregnancy.

Do not take ARROW - NIFEDIPINE XR if you are breastfeeding.

ARROW - NIFEDIPINE XR passes into breast milk and may affect your baby.

Do not take ARROW - NIFEDIPINE XR if the expiry date (Exp.) printed on the pack has passed.

It may not work well if you do.

Do not take ARROW - NIFEDIPINE XR if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have, or have had, the following medical conditions:

- heart failure
- other heart or blood vessel disorders

- low blood pressure
- liver disease
- diabetes
- blockage of your oesophagus or intestine
- prolonged diarrhoea
- surgical operations carried out on your bowel.

Tell your doctor if you are pregnant or intend to become pregnant.

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

Taking other medicines

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

Some medicines may be affected by ARROW - NIFEDIPINE XR, or may affect how well it works. These include:

- rifampicin, a medicine used to treat tuberculosis and certain types of infections
- cimetidine and cisapride, medicines used to treat reflux and/or ulcers
- digoxin, a medicine for controlling the rate and rhythm of heartbeats in atrial fibrillation or heart failure
- medicines used to treat irregular heartbeats such as quinidine and some beta-blockers
- medicines used to treat epilepsy such as phenytoin
- other medicines used to treat high blood pressure or angina
- quinupristin and dalfopristin, antibiotics for specific infections (e.g. methicillin resistant *Staphylococcus aureus* infection)
- warfarin, a medicine used to treat and prevent blood clots
- erythromycin, an antibiotic used to treat infections in different parts of the body caused by bacteria
- medicines used to treat HIV such as amprenavir, indinavir, nelfinavir, ritonavir or saquinavir
- oral medicines used to treat fungal infections
- tacrolimus, an immunosuppressant.

Your doctor can tell you what to do if you are taking any of these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - NIFEDIPINE XR.

You should not eat grapefruit or drink grapefruit juice in large quantity while you are taking ARROW - NIFEDIPINE XR because this can cause unwanted changes in the blood pressure lowering effect of the tablets.

If you have not told your doctor about any of the above, tell them before you start taking ARROW - NIFEDIPINE XR.

How to take ARROW - NIFEDIPINE XR

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet.

How much to take ARROW - NIFEDIPINE XR

The usual starting dose of ARROW - NIFEDIPINE XR is 30 mg (one tablet) each day. Your doctor may increase the dose slowly over several weeks depending on how you respond to this medicine.

How to take ARROW - NIFEDIPINE XR

Swallow the tablet with a glass of water. ARROW - NIFEDIPINE XR Tablets should not be chewed or broken up.

When to take ARROW - NIFEDIPINE XR

Take the tablet at about the same time of each day.

Taking your tablet at the same time each day will have the best effect on your conditions. It will also help you to remember when to take it.

How long to take ARROW - NIFEDIPINE XR

ARROW - NIFEDIPINE XR helps control your condition, but does not cure it. Therefore, you must take it every day. Continue taking your tablets for as long as your doctor tells you to.

If you forget to take ARROW - NIFEDIPINE XR

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember (if less than 12 hours to the next dose), and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much ARROW - NIFEDIPINE XR (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and

Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - NIFEDIPINE XR Tablets.

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

Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include feeling dizzy and fainting due to drop in blood pressure, irregular or rapid heart beats, shortness of breath and even loss of consciousness.

While you are taking ARROW - NIFEDIPINE XR

Things you must do

Take ARROW - NIFEDIPINE XR exactly as told by your doctor.

If you do not follow your doctor's instruction, you may not get control of your blood pressure or relief from your angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are taking ARROW - NIFEDIPINE XR.

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - NIFEDIPINE XR.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - NIFEDIPINE XR.

If you become pregnant while taking ARROW - NIFEDIPINE XR, tell your doctor immediately.

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 use ARROW - NIFEDIPINE XR to treat any other conditions unless your doctor tells you to.

Do not change the dose of your ARROW - NIFEDIPINE XR without checking with your doctor.

Do not give ARROW - NIFEDIPINE XR to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking ARROW - NIFEDIPINE XR until you know how it affects you.

ARROW - NIFEDIPINE XR can cause dizziness, light-headedness or fainting in some patients who have low blood pressure, especially when they first start taking the medicine, change dose, or drink alcohol.

Make sure you know how you react to ARROW - NIFEDIPINE XR before driving a car, operating machinery, or do anything else that could be dangerous if you are affected.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. This may be more noticeable when you first start taking ARROW - NIFEDIPINE XR.

Standing up slowly, especially when you get up from lying down or sitting, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - NIFEDIPINE XR.

Like other medicines, ARROW - NIFEDIPINE XR Tablets can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness or light-headedness
- feeling sick (nausea)
- flushing
- loss of energy, unusual tiredness or weakness
- constipation
- numbness in hands and feet

- swelling of the ankles or legs.

These are the more common side effects of ARROW - NIFEDIPINE XR. They are usually mild and often go away with time.

Bleeding, tender or swollen gums may occur some time after starting ARROW - NIFEDIPINE XR. Muscle pain, trembling, visual disturbances and an increase in the need to pass water may also occur.

Occasionally, the treatment of high blood pressure may lead to slight breast swelling in older men. This side effect goes away when the treatment is stopped.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heartbeats
- fainting
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These side effects are rare but can be serious. You may need medical attention.

If any of the following happen after taking ARROW - NIFEDIPINE XR, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body, shortness of breath, wheezing, or trouble breathing
- signs of liver problems such as yellowing of the skin and/or eyes (jaundice).

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

Very rarely, some people experience a purple/brown discolouration of the skin or redness, flaking and itching of the skin. Also, it has been reported that some people develop a rash or blistering of the skin when they are exposed to sunlight.

In a small number of cases of *in vitro* fertilisation, medicines like nifedipine appeared to have interfered with the normal function of sperm. This effect went away after the medicine was stopped. In those men who are taking ARROW - NIFEDIPINE XR and are repeatedly unsuccessful in fathering a child by *in vitro* fertilisation, the medicine should be considered as one of the possible causes if no other explanation can be found.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking ARROW - NIFEDIPINE XR

Storage

Keep ARROW - NIFEDIPINE XR 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.

Keep ARROW - NIFEDIPINE XR in a cool, dry place where the temperature stays below 25°C.

Keep your tablets in the blister packs until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Do not store ARROW - NIFEDIPINE XR or other medicines in the bathroom or near a sink.

Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - NIFEDIPINE XR, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

ARROW - NIFEDIPINE XR comes in two strengths of tablets:

- ARROW - NIFEDIPINE XR 30: round, pale red tablet marked "30" on one side
- ARROW - NIFEDIPINE XR 60: round, pale red tablet marked "60" on one side.

Each blister pack contains 30 tablets.

Ingredients

The active ingredient in ARROW - NIFEDIPINE XR is nifedipine.

- each ARROW - NIFEDIPINE XR 30 contains 30 mg of nifedipine
- each ARROW - NIFEDIPINE XR 60 contains 60 mg of nifedipine.

The tablets also contain

- purified talc

- povidone
- lactose
- carbomer 934P
- hypromellose
- silicon dioxide
- magnesium stearate
- titanium dioxide
- iron oxide red CI77491
- macrogol 4000
- Eudragit E100.

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

ARROW - NIFEDIPINE XR is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited
PO Box 128244, Remuera
Auckland, New Zealand.

Date of preparation

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