

ADALAT® OROS

(Add-a-lat Or-us)

nifedipine

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Adalat Oros. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet is for Adalat Oros. It is different from the leaflet for other forms of Adalat products.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Adalat Oros against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ADALAT OROS IS USED FOR

Adalat Oros is used either to treat high blood pressure or to prevent a type of angina (chest pain), known as chronic stable angina.

Adalat Oros is not used for the relief of a sudden attack of angina or to manage unstable angina.

Adalat Oros 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.

Adalat Oros is specially designed to allow the slow release of the active substance from the tablet after it is taken. It is composed of a strong outer shell which does not dissolve in the body and is excreted in the faeces. It is normal to find these "ghost-tablets" in the faeces. The active substance contained in them has been absorbed by the body before excretion.

Your doctor, however, may prescribe Adalat Oros for another purpose.

Ask your doctor if you have any questions about why Adalat Oros has been prescribed for you.

BEFORE YOU TAKE ADALAT OROS

When you must not take it

Do not take Adalat Oros if you have an allergy to:

- nifedipine, the active ingredient in Adalat Oros
- any of the ingredients listed at the end of this leaflet
- active substances similar to nifedipine such as: amlodipine, felodipine and isradipine.

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
- rash, itching or hives on the skin.

Do not take Adalat Oros if you are in cardiogenic shock (very low blood pressure due to a failing heart). Tell your doctor if you have had a heart attack in the last week or so.

Do not take Adalat Oros if you have a Kock Pouch or ileostomy (a surgically created reservoir in the small intestine).

Do not take Adalat Oros if you are taking another medicine containing the active substance rifampicin, an antibiotic used to treat tuberculosis and other serious infections.

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Adalat Oros passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

Do not take tablets that show visible signs of deterioration (e.g. are broken or discoloured).

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- heart failure
- other heart or blood vessel disorders
- low blood pressure
- stroke
- mini-stroke (also known as TIA or transient ischaemic attack)
- liver disease
- diabetes
- narrowing of your oesophagus or intestine, e.g. due to previous injury, infection or surgery
- prolonged diarrhoea, e.g. due to Crohn's disease or ulcerative colitis

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Adalat Oros.

Tell your doctor if you eat grapefruit or drink grapefruit juice regularly, including in the last 3 days before starting Adalat Oros. You should not have grapefruit while you are taking Adalat Oros because this can cause unwanted changes in the blood pressure lowering effect of the tablets.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including those that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines and Adalat Oros may interfere with each other. Examples are given below but this is not a complete list. Talk to your doctor or pharmacist if you have any questions.

Medicines to be careful with or avoid while taking Adalat Oros 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

These medicines may be affected by Adalat Oros or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking Adalat Oros.

HOW TO TAKE ADALAT OROS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Do not remove tablets from the blister pack until you are ready to take them.

If you do not understand the instructions on the pharmacist label, ask your doctor or pharmacist for help.

How much to take

The correct dose of Adalat Oros to take has been decided by your doctor. Make sure you follow the instructions given to you by your doctor.

The usual dose is 30 mg or 60 mg once daily. Your doctor may increase the dose if required.

How to take it

Immediately after removing a tablet from the blister pack, swallow it whole with some liquid.

Do not break or chew the tablets.

When to take it

Take Adalat Oros once a day, at about the same time each day. Adalat Oros can be taken either with or without a meal.

How long to take it

Your doctor will determine how long you should take Adalat Oros tablets. Do not stop taking the tablets unless you are told to do so by your doctor.

If you forget to take it

If you forget to take your daily dose of Adalat Oros at the right time and remember in less than 12 hours, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

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

If you have missed several doses, consult your doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (Australia: 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too many Adalat Oros tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of an overdose include feeling dizzy and fainting due to drop in blood pressure, irregular or rapid heart beats, shortness of breath, shock and loss of consciousness.

WHILE YOU ARE TAKING ADALAT OROS

Things you must do

Take Adalat Oros 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Adalat Oros.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are taking Adalat Oros.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Adalat Oros.

The use of Adalat Oros may affect the results of certain laboratory tests or x-rays.

If you are about to have any tests or x-rays, tell your doctor that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other medical conditions unless your doctor says so.

Do not eat grapefruit or drink grapefruit juice while you are taking this medicine.

Grapefruit can cause unwanted changes in the blood pressure lowering effect of Adalat Oros.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Adalat Oros affects you.

It may cause dizziness or fainting in some patients, especially when they first start taking the medicine, change dose, or drink alcohol.

If you have angina, be careful not to overdo physical activities when you first start taking Adalat Oros. 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 Adalat Oros.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

The following list includes the common side effects of your medicine. They are usually mild and short-lived.

- headache
- feeling dizzy
- fast or irregular heartbeats
- flushing
- constipation
- unusual tiredness or weakness
- generally feeling unwell
- general swelling and/or swelling of the arms, ankles or legs

Your doctor may need to monitor your liver function, as Adalat Oros can increase your liver enzymes. You may not experience any specific symptoms.

If any of the following happen, stop taking Adalat Oros and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- 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)
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These serious side effects are not common. If you have these side effects, you may need urgent medical attention.

There have been reports of 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 very rare cases, the undissolved shell of the Adalat Oros tablet or "ghost-tablets" may not be excreted in the faeces and may collect in the stomach. Tell your doctor if you experience symptoms of bowel blockage. Surgery may be necessary to remove these shells.

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 Adalat Oros 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING ADALAT OROS

Storage

Keep the tablets in the pack until it is time to take them.

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

Keep the medicine in a cool dry place.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep the tablets where children cannot reach them.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

- Adalat Oros 20 mg tablets are round, biconvex film-coated tablets in rose-pink colour marked with "Adalat 20" on one side and a pin-prick hole on the other side to aid in delivery of your medicine. The tablets are supplied in blister packs of 30 tablets, with each tablet containing 20 mg of nifedipine.
- Adalat Oros 30 mg tablets are round, biconvex film-coated tablets in rose-pink colour marked with "30" on one side and a pin-prick hole on the other side to aid in delivery of your medicine. The tablets are supplied in blister packs of 30 tablets, with each tablet containing 30 mg of nifedipine.
- Adalat Oros 60 mg tablets are round, biconvex film-coated tablets in rose-pink colour marked with "60" on one side and a pin-prick hole on the other side to aid in delivery of your medicine. The tablets are supplied in blister packs of 30 tablets, with each tablet containing 60 mg of nifedipine.

Ingredients

Active Ingredient per tablet:

- Adalat Oros 20 - nifedipine 20 mg
- Adalat Oros 30 - nifedipine 30 mg
- Adalat Oros 60 - nifedipine 60 mg

Inactive ingredients:

- polyethylene oxide
- magnesium stearate
- sodium chloride
- hypromellose
- iron oxide red (CI 77491)
- hydroxypropylcellulose
- cellulose acetate
- macrogol 3350
- titanium dioxide
- propylene glycol

Supplier

Made in Germany for:
Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian Registration Numbers

- ADALAT OROS 20 -
AUST R 60101
- ADALAT OROS 30 -
AUST R 76041
- ADALAT OROS 60 -
AUST R 76040

Date of preparation

June 2013

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

® Registered Trademark of Bayer AG, Germany

© Bayer Australia Ltd

All rights reserved

