

Adefin XL

nifedipine modified release tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ADEFIN XL tablets. 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 ADEFIN XL. It is different from the leaflet for other forms of ADEFIN products.

It is not to be used in relation to any other product, which may also contain the same active ingredient.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ADEFIN XL against the benefits expected for you.

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

Please read this leaflet carefully and keep it with your medicine.

You may need to read it again.

What ADEFIN XL is used for

ADEFIN XL is used to:

- treat high blood pressure
- prevent chronic stable angina, a type of angina (chest pain).

ADEFIN XL is not used to relieve sudden attacks of angina or to manage unstable angina.

ADEFIN XL contains the active ingredient nifedipine which belongs to a group of medicines called calcium channel blockers.

Calcium channel blockers work by opening up blood vessels in the body to lower blood pressure and improve the supply of blood and oxygen to the heart.

ADEFIN XL tablets are specially designed with a strong outer shell. This outer shell allows the medicine to be released slowly into the body over a longer period of time after it is taken. The outer shell is excreted or passed out in the faeces (or bowel motions), as it does not dissolve in the body. Therefore, it is normal to find a "tablet-like" object in the faeces. The active substance contained in them has been absorbed by the body before excretion.

Ask your doctor if you have any questions about why ADEFIN XL has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take ADEFIN XL

When you must not take it

Do not take ADEFIN XL if you are allergic to:

- medicines containing nifedipine (eg. in Adefin XL, Adefin)
- medicines similar to nifedipine such as amlodipine (Norvasc), felodipine (Plendil, Felodur), lercanidipine (Zanidip), nimodipine (Nimotop)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Skin rash, itching or hives;
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
- Wheezing or shortness of breath.

Do not take ADEFIN XL if you are in cardiogenic shock (very low blood pressure due to a failing heart).

Symptoms of cardiogenic shock include rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting.

Do not take ADEFIN XL if you have had a heart attack in the last week or so.

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

Do not take ADEFIN XL if you are taking any medicine containing rifampicin (Rifadin, Rimycin), an antibiotic used to treat tuberculosis and other serious infections.

Do not take ADEFIN XL if you are pregnant or plan to become pregnant.

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

Do not take ADEFIN XL if you are breastfeeding or plan to breastfeed.

ADEFIN XL passes into breast milk and may affect your baby.

Do not take ADEFIN XL after the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take ADEFIN XL if the packaging shows signs of tampering or the tablets are broken, discoloured or show any other sign of deterioration.

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 medical conditions, especially the following:

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

- kidney disease
- any surgical operations carried out on your bowel.

If you have not told your doctor about any of the above, tell him/her before you start taking ADEFIN XL.

Tell your doctor if you eat grapefruit or drink grapefruit juice regularly, including in the last 3 days before starting ADEFIN XL.

You should not have grapefruit juice while you are taking ADEFIN XL 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 any that you can buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by ADEFIN XL or may 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

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 ADEFIN XL.

How to take ADEFIN XL

Follow all directions given to you by your doctor and 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 pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

Your doctor will decide the right dose for you.

This may depend on your condition, age, other medicines you are taking and how you respond to ADEFIN XL.

For the treatment of high blood pressure, the dose range is between 20 mg to 120 mg once daily.

For the treatment of chronic stable angina, the dose range is between 30 mg to 90 mg once daily.

Elderly people over 65 years of age and people with liver problems may require lower doses.

How to take it

Immediately after removing a tablet from the blister pack, swallow ADEFIN XL tablets whole with some water.

ADEFIN XL tablets must not be chewed, halved or broken up.

Your chances of getting unwanted side effects are increased if you chew or break the tablets. ADEFIN XL tablets are specially designed with a strong outer shell, which allows the medicine to be released slowly into the body.

When to take it

Take ADEFIN XL once a day, about the same time each day. The tablets should generally be taken in the morning.

ADEFIN XL can be taken either with or without a meal.

How long to take it

Keep taking ADEFIN XL for as long as your doctor recommends.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forgot to take it

If you forget to take your daily dose of ADEFIN XL 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.

This may increase the chance of you getting an unwanted side effect.

If you have missed several doses, consult your doctor.

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

If you have trouble remembering to take your ADEFIN XL, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 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 much ADEFIN XL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of an overdose include dizziness and fainting due to a drop in blood pressure; irregular or rapid heartbeats; shortness of breath and even loss of consciousness.

While you are taking ADEFIN XL

Things you must do

Take ADEFIN XL exactly as prescribed by your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ADEFIN XL

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking ADEFIN XL.

If you are about to have any blood tests or x-rays, tell your doctor that you are taking ADEFIN XL.

It may interfere with the results of some tests.

If you become pregnant while taking ADEFIN XL, tell your doctor immediately.

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

Things you must not do

Do not take ADEFIN XL to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.

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 ADEFIN XL.

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

Make sure you know how ADEFIN XL affects you before driving a car, operating machinery, or do anything else that could be dangerous.

ADEFIN XL may cause dizziness or fainting in some people, 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 ADEFIN XL.

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 ADEFIN XL.

ADEFIN XL helps most people, but it may have unwanted effects in some people.

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

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

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

Your doctor may need to monitor your liver function, as ADEFIN XL can increase your liver enzymes.

You may not experience any specific symptoms.

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

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

These are very serious side effects. If you have these side effects 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. Tell your doctor if you experience any of these symptoms.

Very rarely, the undissolved tablet shell may not pass out in the faeces and collect in the stomach. Tell your doctor if you experience symptoms of bowel blockage. Surgical intervention may be necessary to remove these shells.

In a small number of cases of in vitro fertilization, medicines like nifedipine may have interfered with the normal function of sperm. This effect went away after the medicine was stopped. In those men who are taking Adefin XL and are repeatedly unsuccessful in fathering a child by in vitro

fertilization, the medicine should be considered as one of the possible causes if no other explanation can be found.

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

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

After taking ADEFIN XL

Storage

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

Heat and moisture can affect ADEFIN XL tablets. Contact with moisture can release the active ingredient (nifedipine) from the tablets. To prevent this, the tablets must be kept in the original pack until immediately before use.

Keep your tablets in a cool dry place, away from sunlight where the temperature stays below 30°C (ADEFIN XL 30) or below 25°C (ADEFIN XL 60).

Do not leave ADEFIN XL in the car or on window sills.

Do not store ADEFIN XL or any other medicine in the bathroom or near a sink.

Keep ADEFIN XL 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 tells you to stop taking ADEFIN XL, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ADEFIN XL is available in two strengths:

- ADEFIN XL 30 - round, pink coloured tablet, with "30" printed in black on one side and blank on the other side.
- ADEFIN XL 60 - round, pink coloured tablet, with "60" printed in black on one side and blank on the other side.

Each pack contains 30 tablets.

Ingredients

The active ingredient in ADEFIN XL is nifedipine.

- Each ADEFIN XL 30 tablet contains 30 mg of nifedipine.
- Each ADEFIN XL 60 tablet contains 60 mg nifedipine.

ADEFIN XL also contains the following inactive ingredients:

- polyethylene oxide
- magnesium stearate

- hypromellose
- iron oxide red CI77491 (E172)
- hydroxypropylcellulose
- cellulose acetate
- macrogol 3350
- titanium dioxide (171)
- propylene glycol
- sodium chloride
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Supplier

ADEFIN XL is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

ADEFIN XL 30 - AUST R 91779

ADEFIN XL 60 - AUST R 91778

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