

ADEFIN XL

Nifedipine 30 mg & 60 mg modified release tablets



What is in this leaflet

Please read this leaflet carefully before you start using ADEFIN XL.

This leaflet answers some common questions about ADEFIN XL.

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

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

ADEFIN XL is used either to treat high blood pressure or to prevent chronic stable angina, one of a number of types of angina.

ADEFIN XL is not used for the relief of a sudden attack of angina.

ADEFIN XL 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.

Your doctor may have prescribed ADEFIN XL for another reason.

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

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

Before you use ADEFIN XL

When you must not use it

Do not use ADEFIN XL if you have an allergy to:

- nifedipine, the active ingredient in ADEFIN XL
- any of the ingredients listed at the end of this leaflet
- active substances similar to nifedipine such as: amlodipine, felodipine, lercanidipine, nimodipine 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, and rash, itching or hives on the skin.

Do not use 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 use ADEFIN XL if you are breast-feeding or plan to breast-feed.

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

Do not use ADEFIN XL if you have had a heart attack in the last 8 days.

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

Do not use ADEFIN XL if you are taking another medicine containing rifampicin, an antibiotic used to treat tuberculosis and other serious infections.

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

The expiry date is printed on the carton and on each blister. If it has expired return it to your pharmacist for disposal.

Do not use this medicine 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 using this medicine, talk to your doctor.

Before you start to use it:

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

Tell your doctor if you are switching from or to immediate release nifedipine capsules or tablets.

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)
- narrowing of the aorta
- liver disease
- diabetes
- kidney disease
- blockage of your oesophagus or intestines
- prolonged diarrhoea (eg. Crohn's disease or ulcerative colitis)
- any surgical operations carried out on your bowel.

You should discuss these medical conditions with your doctor to check whether ADEFIN XL is suitable for you.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using ADEFIN XL.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking ADEFIN XL.

Some medicines may interfere with ADEFIN XL. These include:

- beta blockers, e.g. metoprolol, atenolol
- medicines used to treat high blood pressure or angina (chest pain), e.g. diltiazem
- medicines used to treat heart disease, e.g. digoxin
- medicines used to treat arrhythmia (fast or irregular heartbeats), e.g. quinidine
- medicines used to treat stomach ulcers, e.g. cimetidine, cisapride
- medicines used to treat bacterial infections, e.g. erythromycin, quinupristin and 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
- medicines used to treat depression, e.g. fluoxetine, nefazodone
- tacrolimus, a medicine used to prevent rejection after organ transplant.

These medicines may be affected by ADEFIN XL or may affect how well it works. You may need to take different medicines.

You should not eat grapefruit or drink grapefruit juice while you are taking ADEFIN XL because this can cause unwanted changes in the blood pressure lowering effect of the tablets.

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 use ADEFIN XL

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

They may differ from the information contained in this leaflet.

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

This medicine is only intended for the use of the consumer it has been prescribed for.

How much to take

The dose varies from person to person.

Your doctor will tell you how much you need to take each day and when to take it.

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

The usual starting dosage is 30 mg once daily. Your doctor may increase the dose slowly over a period of time, depending on how you respond to this medicine.

How to take it

Swallow ADEFIN XL tablets whole with some water. The 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

The tablets should generally be taken in the morning.

ADEFIN XL tablets 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 it does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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 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 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, ask your doctor or pharmacist.

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

While you are using ADEFIN XL

Things you must do

Take ADEFIN XL exactly as prescribed by your doctor.

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

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

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

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 affect the results of some tests.

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 these "ghost-tablets" in the faeces.

Things you must not do

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

Do not give ADEFIN XL to anyone else, even if they have the same condition as you.

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 ADEFIN XL 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 ADEFIN XL.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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 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 heartbeats, shortness of breath and even loss of consciousness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using

ADEFIN XL.

This medicine helps most people, but it may have unwanted effects in a few people. 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.

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

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
- constipation
- feeling dizzy
- flushing
- 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 ADEFIN XL can increase your liver enzymes.

You may not experience any specific symptoms.

Swelling at the back of the throat can occur, which may cause difficulty in talking or breathing.

Tell your doctor if this occurs; you may need urgent medical attention.

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 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)
- 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 may collect in the stomach. Surgical intervention may be necessary to remove these shells. Tell your doctor if you experience symptoms of bowel blockage.

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 Adefin XL 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 adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them..

After using ADEFIN XL

Storage

Keep your 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 your tablets in a cool dry place where the temperature stays below 25°C.

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

ADEFIN XL 30 mg tablets are round, biconvex film-coated tablets, pink in colour marked with "30" on one side. The tablets are supplied in blister packs of 30 tablets, with each tablet containing 30 mg of nifedipine.

ADEFIN XL 60 mg tablets are round, biconvex film-coated tablets, pink in colour marked with "60" on one side. The tablets are supplied in blister packs of 30 tablets, with each tablet containing 60 mg of nifedipine.

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 of nifedipine.

Adefin XL also contains the following inactive ingredients:

- hypromellose

- polyethylene oxide
- magnesium stearate
- sodium chloride
- iron oxide red (E172/CI 77491)
- cellulose acetate
- macrogol 3350
- hydroxypropyl cellulose
- propylene glycol
- titanium dioxide (E171/CI 77891)
- Black printing ink

ADEFIN XL is lactose, gluten and sugar free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Sponsor Details

ADEFIN XL is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Preparation

This leaflet was revised on 12 October 2018
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