



PACKAGE LEAFLET: INFORMATION FOR THE USER

Adipine® XL 30 mg & 60 mg Prolonged Release Tablets Nifedipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Adipine is and what it is used for
2. What you need to know before you take Adipine
3. How to take Adipine
4. Possible side effects
5. How to store Adipine
6. Contents of the pack and other information

1. What Adipine is and what it is used for

Adipine XL Prolonged Release Tablets contain nifedipine which belongs to a group of medicines called calcium- channel blockers that act on the cardiovascular system (the heart and blood vessels). Adipine XL is used to treat high blood pressure or angina (chest pain). They are called prolonged release tablets because they are manufactured in a way that allows the nifedipine to be released and slowly absorbed by your body over a period of several hours.

For high blood pressure: Adipine XL works by relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.

For angina: Adipine XL works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks will be less severe and less frequent if there is less strain on the heart.

2. What you need to know before you take Adipine

Do not take Adipine:

- if you are allergic to nifedipine, other calcium-channel blockers (e.g verapamil, diltiazem or felodipine) or any of the other ingredients in Adipine (listed in section 6)
- if you have been told that you have a narrowing (stenosis) of the aortic valve in your heart
- if you have experienced a collapse which was caused by a heart problem (cardiogenic shock), during which you became breathless, pale and had a cold sweat and dry mouth
- if you get a sudden angina attack. Adipine will not help relieve symptoms of angina quickly
- if you have unstable angina
- if you suffer from inflammation of the bowel or intestines (such as Crohn's disease), oesophageal (gullet) obstruction or have in the past had an obstruction or narrowing of the intestine
- if you have a liver disease that prevents your liver from working properly
- if you have had a heart attack during the last month or to treat a heart attack
- if you are taking the antibiotic rifampicin (used to treat tuberculosis)
- if your blood pressure continues to rise despite treatment (malignant hypertension)
- if you have a Kock pouch (a type of ileostomy - a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut

Warnings and Precautions:

- if you suffer from low blood pressure and you were prescribed Adipine for your angina. Your blood pressure may be decreased further by this treatment
- if you experience chest pains when you first start taking Adipine, contact your doctor immediately. Your doctor may wish to change your treatment
- if you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve)
- if you are pregnant
- if you are breast-feeding. If you need to take Adipine, you should stop breast-feeding before you start to take this medicine
- if you are diabetic, the treatment for your diabetes may need to be adjusted. If you have any questions about this, ask your doctor
- if you are receiving kidney dialysis and have very high blood pressure with low blood volume, you might experience a sudden drop in blood pressure when you take Adipine
- if your liver is not working properly. Your doctor may need to do some blood tests. You may also be given a lower dose of Adipine
- if you are taking other drugs to treat high blood pressure (e.g. beta-blockers). If you are changing from a beta-blocker to nifedipine, you should gradually reduce your beta-blocker after discussion with your doctor
- if you are giving a urine sample. Adipine may interfere with the results of certain urine tests
- if you are to have a barium contrast x-ray (barium meal). These tablets may affect the results of the test
- if you notice increased breathlessness
- if you notice swelling of the ankles
- if your chest pain (angina) gets worse (comes on more often or more severely) over a matter of hours or days. You may be advised not to take Adipine
- if you are male and have been unsuccessful in fathering a child by in vitro fertilisation. Medicines like Adipine have been shown to impair sperm function.

Other medicines

Before starting treatment, tell your doctor or pharmacist if you are taking or have recently taken **any other medicines**, including medicines obtained without a prescription. If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Adipine. This is especially important if you are likely to have an anaesthetic or an operation.

In particular, tell your doctor if you are taking:

- other drugs to treat high blood pressure
- cimetidine, to treat stomach ulcers
- digoxin, diltiazem, quinidine, or beta-blockers, used to treat heart conditions
- the antibiotic rifampicin
- combination treatment quinupristin/dalfopristin
- cisapride, a drug used to speed up the movement of food through the gullet and stomach
- magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure)
- the antibiotics erythromycin, or anti-fungal medicines ketoconazole, itraconazole or fluconazole
- indinavir, nelfinavir, ritonavir, amprenavir or saquinavir, used to treat HIV infection
- the antidepressant drugs fluoxetine and nefazodone
- tacrolimus, an immunosuppressant used to prevent the rejection of transplant organs
- phenytoin, carbamazepine and valproic acid, used for the treatment of epilepsy
- the barbiturate phenobarbital, used primarily to treat insomnia and anxiety

Taking Adipine with food and drink

You can take Adipine with or without food.

Do not drink grapefruit juice or eat grapefruit while taking Adipine.

Do not start taking Adipine within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking Adipine. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

One tablet of Adipine 30 contains 24 mg salt (sodium chloride). Tell your doctor if you are on a low-salt diet.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You may be able to use Adipine but only after special consideration and agreement by your doctor.

Do not take Adipine if you are breast-feeding. If you need to take Adipine, you should stop breast-feeding before you start taking this medicine.

Driving and using machines:

If you feel dizzy, faint, extremely tired or have visual disturbances after taking Adipine, then do not drive or operate machinery.

This may be more likely when you first start treatment, if you change tablets, or if you have drunk alcohol.

Adipine XL tablets contain Lactose

Adipine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Adipine

Always take Adipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and the Elderly:

- **Dose for high blood pressure:** the recommended dose is 1 tablet, once a day.
- **Dose for angina:** the dose depends on your individual requirements. Your doctor will decide how much you should take.
- **Swallow the tablets whole. Do not bite, chew or break them** – if you do they will not work properly. If you have difficulty swallowing tablets, consult your doctor as he or she may wish to change your medicine.
- **Continue to take these tablets** for as long as your doctor has told you to.

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Take your dose at the same time each day, preferably in the morning.
Take your tablets with a glass of water. Do not take them with grapefruit juice.
You can take Adipine XL with or without food.
You may see what looks like a complete tablet in the toilet or in your stools. This is normal – it's the outer shell of the tablet which is not digested by the body.

Use in children and adolescents: Adipine XL is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

If you take more Adipine than you should

If you accidentally take more Adipine than you should, contact your nearest casualty department immediately. Remember to take the pack and any remaining tablets with you. Taking too many tablets may cause your blood pressure to become too low and your heartbeats to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take Adipine

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a missed dose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Adipine can cause side effects, although not everyone gets them. **Allergic reactions**, although serious, have been reported in rare cases. If you experience any of the following, contact your doctor or casualty department immediately and do not take the next dose:

- severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway)
- other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome)
- fast heart beat (tachycardia)
- itching (possibly severe), rash, hives or skin redness affecting your whole body
- mild to moderate allergic reactions
- wheezing or breathing difficulties
- skin reaction or blistering/peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Toxic Epidermal Necrolysis)
- yellowing of the whites of the eyes or skin (jaundice)
- a more severe decrease in a specific class of white blood cell (agranulocytosis)

If you experience **chest pains** when you first start taking Adipine, contact your doctor immediately.

The following side effects have also been reported, if you do experience any of these side effects they will usually go away when treatment is stopped.

Common (may affect up to 1 in 10 people):

- headache
- flushing
- general feeling of being unwell
- constipation
- swelling, particularly of the ankles and legs.

Uncommon (may affect up to 1 in 100 people):

- stomach pain (abdominal pain)
- unspecific pain
- chills
- low blood pressure when rising to the standing position (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- irregular heartbeat (palpitations)
- a dry mouth
- indigestion or upset stomach
- wind (flatulence)
- feeling sick (nausea)
- muscle cramps
- joint swelling
- sleep disorders
- anxiety or nervousness
- reddening of the skin
- nose bleeds
- nasal congestion
- sensation of spinning or whirling motion (vertigo)
- migraine

- dizziness
- trembling
- an increased need to urinate
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- blurred vision
- temporary increase in certain liver enzymes

Rare (may affect up to 1 in 1,000 people):

- pins and needles
- inflammation of the gums
- tender or swollen gums which may bleed
- changes in mood

Not known (frequency cannot be estimated from the available data):

- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal
- difficulty swallowing
- abdominal pain, caused by obstruction of the gut or ulcers in the gut
- vomiting
- a reduction in the number of white blood cells (leucopenia)
- a more severe decrease in a specific class of white blood cell (agranulocytosis)
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hypoesthesia)
- drowsiness (somnolence)
- eye pain
- chest pain (angina pectoris)
- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- yellowing of the whites of the eyes or skin (jaundice)
- sensitivity to light (photosensitivity allergic reaction)
- small, raised areas of bleeding in the skin (palpable purpura)
- joint pain
- muscle pain
- depression

The development of breast tissue in older men on long term therapy and heart attacks have also been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the YellowCard Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adipine

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Keep the blister in the outer carton.
- Do not use Adipine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Adipine contains:

- The active substance is nifedipine.
- The other ingredients are povidone K30, lactose monohydrate, talc, hypromellose (E464), magnesium stearate, carbomer 974P, colloidal anhydrous silica, macrogol 4000, dimethylaminoethyl methacrylate-butyl methacrylate-methyl methacrylate copolymer, red iron oxide (E172) and titanium dioxide (E171).

What Adipine look like and the contents of the pack:

Adipine XL 30 mg and 60 mg Prolonged Release Tablets are pale red with a round and biconvex shape, marked on one side with "30" or "60" respectively. They are available in calendar blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer.

The Marketing Authorisation holder and manufacturer is Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

Is this leaflet hard to see or read? Phone 0161 488 5555 for help.

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