

Package leaflet: Information for the user

Adalat® LA 30 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 Adalat LA is and what it is used for
2. What you need to know before you take Adalat LA
3. How to take Adalat LA
4. Possible side effects
5. How to store Adalat LA
6. Contents of the pack and other information

1. What Adalat LA is and what it is used for

Adalat LA contains nifedipine, which belongs to a group of medicines called *calcium antagonists*.
Adalat LA is used to treat high blood pressure or angina (chest pain).

For high blood pressure: Adalat LA 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: Adalat LA 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 Adalat LA

Do not take Adalat LA:

- **If you have had a heart attack** within the last month.
- **If you get a sudden angina attack.** Adalat LA will not help relieve symptoms of angina quickly.
- **If you have unstable angina.**
- **If you are allergic** to nifedipine, any other similar medicines (known as *dihydropyridines*) or any of the other ingredients of this medicine (listed in section 6).
- **If you are taking rifampicin**, an antibiotic.
- **If you have a liver disease** that prevents your liver from working properly.
- **If you have inflammation of the bowel or intestines**, such as Crohn's disease.
- **If you have an obstruction or narrowing in your intestines** or have had this in the past.
- **If you have ever had an obstruction in the gullet** (the *oesophagus* - the tube connecting the throat to the stomach).

- **If you have been told that you have a narrowing of the aortic heart valve (*stenosis*).**
 - **If you have ever had a collapse** caused by a **heart problem** (*cardiogenic shock*), during which you became breathless, pale and had a cold sweat and dry mouth.
 - **If you have a “Kock pouch”** (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.
 - **If your blood pressure continues to rise** despite treatment (*malignant hypertension*).
- **Tell your doctor and do not take Adalat LA if any of these apply to you.**

Warnings and precautions

Talk to your doctor before taking Adalat LA

- **If you have low blood pressure** and you were prescribed Adalat LA for your angina. Your blood pressure may be decreased further by this 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 Adalat LA, you should stop breast-feeding before you start to take this medicine.
 - **If you are a diabetic.** The treatment for your diabetes may need to be adjusted. If you have any questions about this, ask your doctor.
 - **If you are on kidney dialysis.** If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take Adalat LA.
 - **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 Adalat LA.
- **Talk to your doctor before you take Adalat LA if any of these apply to you.**

Tell your doctor:

- **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 Adalat LA.
 - **If you have chest pains after taking your first dose** of Adalat LA. Your doctor may wish to change your treatment.
 - If you notice increased breathlessness.
 - **If you notice swelling of the ankles.**
- **Tell your doctor before you take the next dose if any of these apply to you.**

Also tell your doctor:

- **If you are giving a urine sample.** Adalat LA 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 are a man who has been unable to father a child** by *in vitro* fertilisation. Drugs like Adalat LA have been shown to impair sperm function.

Other medicines and Adalat LA

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines may affect the way Adalat LA works. **Tell your doctor** if you are taking:

- Other medicines to treat high blood pressure (angiotensin-II blockers i.e. irbesartan, candesartan)
- **Rifampicin** (an antibiotic).
- **Cimetidine** (to treat stomach ulcers).
- **Digoxin, diltiazem, verapamil, quinidine, flecainide** or **beta-blockers** (to treat heart conditions).
- **Quinupristin/dalfopristin** (a combination antibiotic).
- **Phenytoin, carbamazepine** or **valproic acid** (to treat epilepsy).
- **Cisapride** (to treat reduced movements of the gullet and stomach).
- **Magnesium sulphate injections during pregnancy** (may cause a severe fall in blood pressure).

- **Erythromycin** (an antibiotic).
- **Ketoconazole, itraconazole or fluconazole** (anti-fungal medicines).
- **Indinavir, nelfinavir, ritonavir, saquinavir or amprenavir** (to treat HIV).
- **Fluoxetine or nefazodone** (to treat depression).
- **Tacrolimus** (to prevent the rejection of transplanted organs).
- **Phenobarbital** (usually used to treat insomnia or anxiety).
- Central alpha1-blockers (doxazosin)
- Antithrombotics (coumarins)
- Platelet aggregation inhibitors (clopidogrel, tirofiban)
- Antisecretory drugs (omeprazole, pantoprazole, ranitidine, cisapride, sirolimus)
- Glucose Lowering drugs (pioglitazone, rosiglitazone, metformin, miglitol, repaglinide, acarbose)
- Herbal medicine (St. John's Wort)
- Other e.g. Diuretics, PDE5 inhibitors, alpha-methyldopa: Nifedipine may increase the blood pressure lowering effect of these concomitantly administered agents.

Adalat LA with food and drink

You can take Adalat LA with or without food.

Do not drink grapefruit juice or eat grapefruit while taking Adalat LA.

Do not start taking Adalat LA 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 Adalat LA. 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 Adalat LA 30 contains 24 mg salt (*sodium chloride*). **Tell your doctor if you are on a low-salt diet.**

Pregnancy and breast-feeding

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 Adalat LA but only after special consideration and agreement by your doctor.

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

Driving and using machines

Adalat LA may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way.

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

3. How to take Adalat LA

Adalat LA is specially formulated so that you only have to take one dose each day.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- **Dose for high blood pressure:** the usual 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. 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 Adalat LA 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:

Adalat LA 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 Adalat LA than you should

→ **Get medical help immediately. If possible, take your tablets or the box with you to show the doctor.**

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 Adalat LA

Take your normal dose immediately and continue taking your tablets at the usual time of day, waiting at least 12 hours before taking the next dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects If you notice:

- 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*)
- shortness of breath (frequency not known) or difficulty breathing
- mild to moderate allergic reactions
- itching (possibly severe), a rash or hives

→ **Contact your doctor immediately and do not take the next dose as these may be the first signs of allergic reaction which may become severe.**

If you develop:

- a skin reaction or blistering/peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (*Toxic Epidermal Necrolysis*)

→ **Contact your doctor immediately before you continue treatment as these may be signs of a severe reaction.**

Less serious side effects

Apart from the side effects listed above, these are the other side effects of Adalat LA, starting with the more common ones:

Common side effects *(These may affect up to 1 in 10 people)*

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

Uncommon side effects *(These may affect up to 1 in 100 people)*

- stomach pain (abdominal pain)
- unspecific pain
- chills
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- irregular heartbeat (palpitations)
- 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
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- blurred vision
- temporary increase in certain liver enzymes

Rare side effects *(These may affect up to 1 in 1,000 people)*

- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums

Other side effects *(Frequency 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

All of these symptoms usually go away when treatment with Adalat LA is stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance Centre (NPC)

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

Other Countries:

Please contact the relevant competent authority.

5. How to store Adalat LA

Keep this medicine out of the sight and reach of children. Do not store above 30°C.

Store your medicine in its original container. Protect from strong light and only remove the tablet from the blister strip when you are about to take it.

Do not use this medicine after the expiry date which is stated on both the outer carton and on each blister strip of tablets after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Adalat LA contains

Adalat LA tablets contain the active ingredient, nifedipine.

Adalat LA tablets also contain cellulose acetate, ferric oxide (E172), hydroxypropyl cellulose, hydroxypropyl methylcellulose, macrogol, magnesium stearate, propylene glycol, titanium oxide (E171).

Each 30 mg tablet also contains 24 mg of sodium chloride (salt) to be taken into consideration by patients on a controlled sodium diet.

What Adalat LA looks like and contents of the pack

Each prolonged-release tablet contains 30 mg of nifedipine. Each tablet is pink and round with a laser hole on one side and marked 'Adalat 30'.

Each pack contains 30 tablets.

Manufacturer

Bayer AG
Kaiser-Wilhelm-Allee 1
51373 Leverkusen, Germany.

Secondary Packed by:

DEEF Pharmaceutical Ind. Co.,
Saudi Arabia - Al Qassim

This leaflet was last revised in August 2016.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists