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What *Adalat LA* is used for

Adalat LA is used to treat hypertension (high blood pressure).

Adalat LA is used to treat angina pectoris (chest pain).

How *Adalat LA* works

Adalat LA contains nifedipine, which belongs to a group of medicines called calcium antagonists.

Adalat LA is used to treat hypertension (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.

Adalat LA is used to treat chronic angina pectoris (chest pain):

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.

Before you use *Adalat LA*

- When you must not use it

- If you are allergic to the active ingredient (nifedipine) or to any of the other ingredients.
- If you are pregnant before week 20.
- If you are breast feeding.
- If you have ever had a collapse caused by a heart/vascular problem (cardiovascular shock).
- If you have a "Kock pouch" (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

- If you are taking rifampicin, an antibiotic

Children and adolescents

The safety and efficacy of *Adalat LA* have not been established in patients aged below 18 years.

Pregnancy and lactation

Do not take *Adalat LA* if you are pregnant. If you are pregnant, think you might be pregnant or are planning a family, tell your doctor before taking *Adalat LA*.

You may be able to use *Adalat LA* after week 20 of your pregnancy, but only after special consideration and agreement by your doctor.

Careful monitoring of blood pressure must be exercised when administered *Adalat* with IV Magnesium Sulfate during pregnancy, as there is a possibility of an excessive fall in blood pressure.

Breastfeeding

Do not take *Adalat LA* if you are breastfeeding. If you need to take *Adalat LA*, you should stop breastfeeding before you start taking the tablets.

In-vitro fertilisation

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

- Before you start to use it

- Take special care with *Adalat LA*: If you have low blood pressure and you were prescribed *Adalat LA* for your angina.
- If you have been told that you have a narrowing of the aortic heart valve (aortic stenosis).
- If you have evident heart failure.
- If you have an obstruction or narrowing in your intestines or food gullet, or have had this in the past. A concretion of foreign material found in the gastrointestinal tract (Bezoar) can occur in very rare cases and

may require surgical intervention.

- If you have a liver disease that prevents your liver from working properly.

Also tell your doctor:

If you are to have a barium contrast x-ray (barium meal). These tablets may affect the results of the test.

• Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines may affect the way *Adalat LA* works.

Tell your doctor if you are taking:

- Other medicines to treat high blood pressure.
- Rifampicin (an antibiotic)
- E.g. Erythromycin or other macrolide antibiotics
- E.g. Ritonavir or other products to treat HIV.
- E.g. Ketoconazole or other anti-fungal medicine (azole anti-mycotics).
- Fluoxetine or nefazodone (to treat depression).
- Quinupristin/dalfopristin (a combination antibiotic).
- Phenytoin, carbamazepine, phenobarbitone or valproic acid (to treat epilepsy).
- Cimetidine (to treat stomach ulcers).
- Cisapride (to treat reduced movements of the gullet and stomach).
- Phenobarbital (usually used to treat insomnia or anxiety).
- Digoxin, quinidine or beta-blockers (to treat heart conditions).
- Tacrolimus (to prevent the rejection of transplanted organs).

How to use *Adalat LA*

• How much to use

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

Always take *Adalat LA* exactly as your doctor has told you.

• Dose for high blood pressure: the usual dose is 1 tablet, once a day:
1 Adalat LA 30 mg tablet once daily (1 x 30 mg/day)
1 Adalat LA 60 mg tablet once daily (1 x 60 mg/day)

• Dose for angina: the usual dose is 1 tablet, once a day:
1 Adalat LA 30 mg tablet once daily (1 x 30 mg/day)
1 Adalat LA 60 mg tablet once daily (1 x 60 mg/day)

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.

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.

Taking *Adalat LA* with food and drink: You can take *Adalat LA* with or without food. Avoid drinking grapefruit juice or eat grapefruit while taking *Adalat LA* : Grapefruit juice is known to increase the blood levels of the active ingredient of *Adalat LA*, nifedipine. This effect can last for at least 3 days.

- When to use it
Take your dose at the same time each day, preferably in the morning.
Take your tablets with a glass of water.
- How long to use it
Continue taking *Adalat LA* for as long as your doctor recommends.
- If you forget to use it
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 the missed dose.
- If you use too much (overdose)
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, build-up of fluid in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

While you are using it

- Things you must do
Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Adalat LA*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Adalat LA* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
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 medication, or if you have drunk alcohol.

Side effects

Like all medicines, *Adalat LA* can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Below are possible side effects listed according to their frequency:

Common: Between 1 and 10 in every 100 people are likely to get these

Uncommon: Between 1 and 10 in every 1000 people are likely to get these
Rare: Between 1 and 10 in every 10,000 people are likely to get these
Not known Frequency cannot be estimated from the available data

Common side effects

- headache
- oedema (swelling, particularly of the ankles and legs)
- vasodilatation (widening of blood vessels)
- constipation
- general feeling of being unwell

Uncommon side effects

- allergic reaction
- allergic swelling (e.g. of face, lips, cheeks, tongue or throat)
- anxiety
- sleep disorders
- vertigo (sensation of spinning or whirling motion dizziness)
- migraine
- dizziness
- tremor (trembling)
- visual disturbances
- tachycardia (abnormally rapid heartbeat)
- palpitations (irregular heartbeat)
- hypotension (low blood pressure)
- syncope (fainting)
- nose bleeds
- nasal congestion (blocked nose)
- gastrointestinal and abdominal pain (stomach pain)
- nausea (feeling sick)
- dyspepsia (indigestion)
- flatulence (wind)
- dry mouth
- transient increase in liver enzymes (temporary increase in certain liver enzymes)
- erythema (reddening of the skin)
- muscle cramps
- joint swelling
- polyuria (excessive passage of urine)
- dysuria (difficulty in passing urine)
- erectile dysfunction (inability to achieve or maintain an erection)
- unspecific pain
- chills

Rare side effects

- pruritus (severe itching)
- urticaria (hives)
- rash
- paraesthesia (tingling or numbness of the hands or feet)
- dysaesthesia (distortion of any sense especially of touch)
- gingival hyperplasia (bleeding, tender or swollen gums)

Side effects where frequency is not known

- agranulocytosis, leucopenia (lack of white blood cells)
- anaphylactic/ anaphylactoid (reaction allergic or allergy-like reaction)
- hyperglycaemia (elevated blood sugar)
- hypoaesthesia (reduced sensitivity to sensory stimuli)
- somnolence (sleepiness)
- eye pain
- chest pain (Angina Pectoris)
- dyspnea (shortness of breath)
- bezoar (concretion of foreign material found in the gastrointestinal tract)
- dysphagia (difficulty in swallowing)
- intestinal obstruction (a blockage of the bowels)
- intestinal ulcer (peptic ulcer)
- vomiting
- Gastrooesophageal sphincter insufficiency
- jaundice
- Toxic Epidermal Necrolysis (severe skin reaction with intense reddening, peeling of the top layer of skin)
- photosensitivity allergic reaction (elevated sensitivity to light)
- palpable purpura (small bleedings in the skin)
- arthralgia (joint pain)
- myalgia (aching muscles)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Adalat LA

- Storage
Keep out of the reach and sight of children.
Do not use *Adalat LA* after the expiry date which is stated on the carton and on each blister strip of tablets.
The expiry date refers to the last day of that month.
Store below 30 °C.

- Disposal
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 to protect the environment.

Product Description

- What it looks like
Adalat LA 30 mg prolonged-release tablets: Round, convex prolonged-release tablet, with pink coat, laser hole on one side.

Adalat LA 60 mg prolonged-release tablet: Round, convex prolonged-release tablet, with pink coat, laser hole on one side.

- Ingredients
 - Active ingredient(s)
One 30 mg tablet contains 30 mg nifedipine
One 60 mg tablet contains 60 mg nifedipine

- Inactive ingredients
 - polyethylene oxide
 - magnesium stearate
 - iron oxide red (E172)
 - cellulose acetate
 - polyethylene glycol
 - hydroxypropyl cellulose
 - propylene glycol
 - titanium dioxide (E171)

- MAL number(s):
MAL20001248A (*Adalat LA* 30 mg)
MAL20001247A (*Adalat LA* 60 mg)

Manufacturer

Bayer Pharma AG
D-51368 Leverkusen,
Germany

Product Registration Holder

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