Adalat® LA 30
Nifedipine

Package leaflet: Information for the patient
Adalat® LA 30 mg prolonged-release tablets
Nifedipine
For use in adults

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 30 MG IS AND WHAT IT IS USED FOR
Adalat LA 30 mg contains the active substance nifedipine.
Adalat LA 30 mg is a medicine for treatment of high blood pressure (calcium antagonist, antihypertensive agent).
Adalat LA 30 mg is used for treatment of high blood pressure with no identifiable cause (essential hypertension).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ADALAT LA 30 MG
Do not take Adalat LA 30 mg
- if you are allergic to nifedipine or any of the other ingredients of this medicine (listed in section 6)
- if you have suffered cardiovascular shock
- if you suffer from narrowing of a heart valve (aortic stenosis)
- if you get symptoms (e.g. pain or chest tightness) while at rest from a condition with poor oxygen supply to your heart muscle (unstable angina pectoris)
- if you have suffered an acute heart attack within the last 4 weeks
- if you have severe narrowing of the gastrointestinal tract
- if you have an artificial bowel outlet (stoma)
- if you are also taking medicines containing the active substance rifampicin (medicines for tuberculosis)
- if you are pregnant, up until the 20th week of pregnancy
- if you are breast-feeding

Adalat LA 30 mg is not intended for use in children and adolescents under 18 years, due to a lack of experience.

Warnings and precautions
Talk to your doctor or pharmacist before taking Adalat LA 30 mg.
Treatment with Adalat LA 30 mg requires regular monitoring by a doctor

- if you have low blood pressure (systolic RR value below 90 mm Hg)
- if you suffer from heart failure that is not being adequately treated (congestive heart failure)
- if you are a dialysis patient with very high blood pressure and low amounts of circulating blood, as a marked drop in blood pressure may occur
- if you are pregnant (see section 2 "Pregnancy, breast-feeding and fertility").

In very rare cases, there have been reports of bezoars (stomach stones) requiring surgery.
Symptoms of intestinal occlusion without a history of gastrointestinal disorders have been reported in isolated cases.
Diarrhoea persisting for several days (e.g. in cases of Crohn's disease, inflammatory bowel disease) may result in incomplete absorption of the active substance, as the drug retention time in the gastrointestinal tract is too short.
The tablet shells of Adalat LA 30 mg prolonged-release tablets may be visible in the gastrointestinal tract when X-ray examinations using contrast media are carried out.
The breakdown of nifedipine, the active substance in Adalat LA 30 mg, involves a specific enzyme system (cytochrome P450 3A4). This enzyme system can be inhibited or intensified by other medicines. This can lead to changes in the effects and side effects of Adalat LA 30 mg (see section 2 "Other medicines and Adalat LA 30 mg").
If you take Adalat LA 30 mg at the same time as other medicines that inhibit this enzyme system, this can lead to enhanced effects, but can also intensify the side effects of Adalat LA 30 mg that may occur. For example, this includes the following medicines:

- certain antibiotics (e.g. erythromycin)
- certain anti-HIV medicines (e.g. ritonavir)
- certain antifungal agents (e.g. ketoconazole)
- nefazodone and fluoxetine (antidepressants)
- quinupristin/dalfopristin (antibiotics)
- valproic acid (a medicine for epilepsy)
- cimetidine (a medicine for stomach and intestinal ulcers)
- tricyclic antidepressants (medicines to treat depression)
- vasodilators (medicines to widen the blood vessels)
- cisapride (medicine for gastrointestinal complaints)

If Adalat LA 30 mg is used at the same time as any of these medicines, blood pressure should be monitored and, if necessary, a reduction of the Adalat LA 30 mg dose should be considered.
The breakdown of nifedipine may be delayed in patients with impaired liver function. The doctor will therefore carefully monitor the course of treatment and, if necessary, reduce the dose.

Other medicines and Adalat LA 30 mg
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

What other medicines affect the way Adalat LA 30 mg works?
The breakdown of nifedipine (the active substance in Adalat LA 30 mg) involves a specific enzyme system (cytochrome P450 3A4). As a result, combined use of medicines that affect this enzyme system can lead to interactions between these medicines and Adalat LA 30 mg.
Both the extent and duration of interactions should be taken into consideration if Adalat LA 30 mg is to be taken together with the following medicines.

Enhancement of the effects and side effects of Adalat LA 30 mg caused by other medicines
If you are using the following other medicines at the same time as Adalat LA 30 mg, your blood pressure should be monitored and, if necessary, a reduction in the Adalat LA 30 mg dose should be considered (see also "Warnings and precautions"):

- certain antibiotics (e.g. erythromycin)
- certain anti-HIV medicines (e.g. ritonavir)
- certain antifungal agents (e.g. ketoconazole)
- fluoxetine and nefazodone (antidepressants)
- quinupristin/dalfopristin (antibiotics)
- valproic acid (a medicine for epilepsy)
- cimetidine (a medicine for stomach and intestinal ulcers)

- tricyclic antidepressants (drugs used to treat depression)
- vasodilators (medicines that dilate the blood vessels)
- cisapride (medicine for gastrointestinal complaints)

Reduction in the effect of Adalat LA 30 mg by other medicines

Rifampicin (medicine for tuberculosis)
Rifampicin speeds up the breakdown of nifedipine (the active substance in Adalat LA 30 mg) within the body. When treating with Adalat LA 30 mg, rifampicin must not be used at the same time, as no effective blood levels of nifedipine will be reached (see also section 2 “Do not take Adalat LA 30 mg”).

Phenytoin (active substance used to treat heart rhythm disorders and epilepsy)
Reduced effectiveness of Adalat LA 30 mg. If both medicines are taken at the same time, the response to nifedipine (the active substance in Adalat LA 30 mg) should be observed and, if appropriate, an increase in the dose of Adalat LA 30 mg should be considered. After phenytoin use is discontinued, the dose of Adalat LA 30 mg may need to be readjusted.

Carbamazepine and phenobarbital (active substances used to treat epilepsy)
If Adalat LA 30 mg is taken at the same time, the effect of Adalat LA 30 mg may be reduced.

How does Adalat LA 30 mg affect the action of other medicines?

Antihypertensive agents:
Adalat LA 30 mg can enhance the antihypertensive (blood pressure-lowering) effect of other medicines belonging to various active substance groups, such as:
- diuretics (medicines to increase urine output)
- beta-receptor blockers (medicines for high blood pressure)
- ACE inhibitors (medicines for high blood pressure)
- angiotensin-I receptor antagonists (medicines for high blood pressure)
- other calcium antagonists (medicines for high blood pressure)
- alpha-receptor blockers (medicines for high blood pressure and heart failure)
- PDE-5 inhibitors (medicines to treat erectile dysfunction)
- alpha-methyldopa (medicines for high blood pressure)

Beta-receptor blockers (group of active substances used to lower blood pressure)
Signs of heart failure may be observed in individual cases in patients treated with beta-receptor blockers at the same time. Your doctor will monitor the progress of treatment carefully in this case.

Digoxin (active substance used to strengthen heart contractions)
The blood concentrations of this medicine may rise. Vigilance is required for signs of a digoxin overdose and, if necessary, the digoxin dose should be reduced by the doctor (depending on measurements of blood digoxin concentrations).

Theophylline (active substance used to widen the bronchial tubes)
The blood concentrations of this medicine may rise.

Vincristine (active substance used to treat tumours)
The excretion of vincristine will be reduced, which may lead to an increase in the side effects of vincristine. Your doctor may prescribe a reduction in the vincristine dose.

Cephalosporins (active substances used to treat infections)
Blood cephalosporin concentrations may be increased.

Quinidine (active substance used to treat cardiac arrhythmias)
In individual cases, Adalat LA 30 mg causes a decrease in quinidine blood concentrations, or a significant rise in quinidine blood concentrations can occur after discontinuing Adalat LA 30 mg (blood quinidine levels must be monitored). In other cases, a rise in the blood nifedipine concentration due to quinidine has been reported. It is therefore recommended to carefully monitor blood pressure when using both medicines at the same time. If necessary, the dose of Adalat LA 30 mg should be reduced.

Tacrolimus (active substance to prevent transplant rejection after liver and kidney transplants, etc.)
If taken at the same time, Adalat LA 30 mg can lead to raised tacrolimus blood levels, with the result that the tacrolimus dose should be reduced in individual cases. Regular monitoring of the blood levels of tacrolimus is recommended.

Adalat LA 30 mg with food and drink
Grapefruit juice may increase the antihypertensive (blood pressure-lowering) effect of Adalat LA 30 mg. This effect persists for at least 3 days after the last consumption of grapefruit juice. You should therefore avoid consuming grapefruit or grapefruit juice around the same time as treatment with Adalat LA 30 mg (see also section 3 “Method of administration”).

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take Adalat LA 30 mg throughout the entire first 20 weeks of pregnancy, as experimental studies with the active substance nifedipine have shown indications of foetal damage. There is no sufficient experience in humans. If pregnancy is confirmed during treatment with Adalat LA 30 mg, a switch in treatment must be made under medical advice. From the 20th week of pregnancy onwards, Adalat LA 30 mg may be taken after careful benefit/risk assessment, when other treatment options are not open to consideration or have proven to be ineffective.
Adalat LA 30 mg must not be used during breast-feeding, as nifedipine (the active substance in Adalat LA 30 mg) passes into breast milk and no experience is available regarding possible effects on the infant. If treatment with Adalat LA 30 mg is necessary during breast-feeding, you should stop breast-feeding.
In individual cases of in vitro fertilisation, calcium antagonists such as nifedipine have been associated with reversible biochemical changes in the head region of spermatozoa, which can lead to impaired sperm function. In cases where repeated in vitro fertilisation has failed and no other explanation can be found, calcium antagonists such as nifedipine should be considered as a possible cause.

Driving and using machines
Treatment with this medicine requires regular medical check-ups. Reactions vary from one person to another and can alter reaction skills to such an extent that the patient›s ability to drive, use machines or work without suitable safeguards may be impaired. This applies particularly at the start of treatment, upon increasing the dose and changing medications and in combination with alcohol.

3. HOW TO TAKE ADALAT LA 30 MG
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage
Unless otherwise prescribed by the doctor, the usual dose for adults is one Adalat LA 30 mg prolonged-release tablet once daily (equivalent to 30 mg nifedipine once daily).
If necessary, the dose can be increased to a maximum of 2 Adalat LA 30 mg prolonged-release tablets once daily (equivalent to 60 mg nifedipine once daily; 60 mg prolonged-release nifedipine tablets are available for this purpose).

Note
Adalat LA 30 mg contains a tablet shell that is excreted in the faeces after release of the active substance.
When using other medicines that inhibit or intensify a certain enzyme system (cytochrome P450 3A4), it may be necessary to adjust the Adalat LA 30 mg dose (see also section 2 “Other medicines and Adalat LA 30 mg”).

Use in certain patient groups

Children and adolescents
Adalat LA 30 mg is not intended for use in children and adolescents under 18 years due to a lack of experience.

Elderly patients (> 65 years)
No dose adjustment is required for patients over 65 years of age.

Patients with impaired liver function
Patients with impaired liver function should be carefully monitored; it may be necessary to reduce the dose as appropriate. In principle, the starting dose is one Adalat LA 30 mg prolonged-release tablet once daily (equivalent to 30 mg nifedipine once daily). This is generally also the maintenance dose.

Patients with impaired kidney function
No dose adjustment is required for these patients.

Method of administration
Oral use.
Take Adalat LA 30 mg prolonged-release tablets with sufficient liquid (e.g. a glass of water), preferably always at the same time of day. The prolonged-release tablets must not be chewed or divided.
Adalat LA 30 mg must not be taken together with grapefruit juice (see also section 2 "Adalat LA 30 mg with food and drink").
Adalat LA 30 mg prolonged-release tablets can be taken independently of meals.

Duration of use
Your treating doctor will decide how long you should take this medicine. Treatment of high blood pressure is usually long-term treatment.
If you have the impression that the effect of Adalat LA 30 mg is too strong or too weak, please talk to your doctor or pharmacist.

If you take more Adalat LA 30 mg than you should
Depending on the extent of overdose, there is a risk that, in addition to a marked drop in blood pressure, the following may occur: impaired consciousness and even deep coma, heart rhythm disorders with slower or faster heart rate, raised blood sugar levels (hyperglycaemia), insufficient blood supply to the major organs and shock caused by heart failure with fluid accumulation in the lungs (pulmonary oedema).
If you suspect an overdose, inform a doctor/emergency doctor immediately, so that he/she can decide on what further measures to take.

If you forget to take Adalat LA 30 mg
Do not take a double dose to make up for a forgotten dose.

If you stop taking Adalat LA 30 mg
Please do not interrupt or stop your treatment with Adalat LA 30 mg without firstly discussing it with your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following categories are used to express the frequency of side effects:
Very common: can affect more than 1 in 10 patients treated
Common : can affect up to 1 in 10 patients treated
Uncommon : can affect up to 1 in 100 patients treated
Rare : can affect up to 1 in 1,000 patients treated
Very rare : can affect up to 1 in 10,000 patients treated
Not known : cannot be estimated from the available data

Possible side effects

Very common:
headache, tissue swelling due to fluid accumulation (oedema).

Common:
dizziness, light-headedness, feeling weak, palpitations, dilation of blood vessels (e.g. facial flushing), constipation, nausea, painful swelling and redness of the arms and legs (erythromelalgia), particularly at the start of treatment, sweating, generally feeling unwell.

Uncommon:
allergic reactions, allergy-related tissue swelling, swelling of the face and lining of the mouth and throat (angioedema), including swelling of the larynx, which may become life-threatening. Itching, rash, anxiety reactions, sleep disorders.
Migraines, muscle tremors, abnormal skin sensations (e.g. tingling, slight numbness), which may be painful in some cases, drowsiness/tiredness, nervousness, visual disturbances, increased pulse rate, decrease in blood pressure, brief blackouts, nosebleeds, stuffy nose, stomach and intestinal pain, abdominal pain, indigestion, flatulence, dry mouth, temporary increase in liver enzyme values, hot

flushes, muscle cramps, swollen joints, muscle pain, increased urinary urgency and an increase in daily urine output, painful urination with difficulty in passing urine. In cases of renal insufficiency, possible temporary worsening of kidney function, erectile dysfunction, nonspecific pain, chills.
Angina pectoris attacks may uncommonly occur, particularly at the start of treatment; patients with existing angina pectoris may experience an increase in the frequency, duration and severity of these attacks.

Rare:
changes in blood count, such as a reduction in red and white blood cells or platelets (anaemia, leukopenia, thrombopenia), bleeding of the skin and mucous membranes with reduced platelet counts (thrombocytopenic purpura), hives, increase in blood sugar levels, gum overgrowth, loss of appetite, bloating, belching, jaundice, allergic photosensitivity of the skin, palpable, pinpoint bleeding into the skin and mucous membranes, male breast enlargement (gynaecomastia), which resolves after discontinuation of Adalat LA 30 mg.

Very rare:
severe decrease in certain white blood cells (agranulocytosis), heart attack, scaly skin inflammation (exfoliative dermatitis).

Frequency not known:
acute allergic systemic reactions that may be life-threatening in some cases (anaphylactic/ anaphylactoid reactions), reduced sensitivity to touch stimuli, eye pain, shortness of breath, stomach stones (bezoars), difficulty in swallowing, symptoms of intestinal obstruction (e.g. flatulence, colic-like pain), intestinal ulcer, vomiting, inflammation of the oesophagus, serious and life-threatening skin changes with peeling and blistering of the outer skin (scalded skin syndrome, toxic epidermal necrolysis), joint pain.
Dialysis patients with high blood pressure and/or decreased blood volumes may experience a more pronounced drop in blood pressure.

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.

5. HOW TO STORE ADALAT LA 30 MG

Keep blister strips in the outer carton in order to protect from light.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and blister strip. The expiry date refers to the last day of that month.

Storage conditions:
Not to be stored above 30°C

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Adalat LA 30 mg contains

- **The active substance** is nifedipine.
  1 Adalat LA 30 mg prolonged-release tablet contains 30 mg nifedipine.
- **The other ingredients** are: cellulose acetate, ferric(III) oxide (E172), hydroxypropyl cellulose, hydroxypropyl methylcellulose, macrogol 3350, macrogol 200 000, macrogol 5 million, magnesium stearate, sodium chloride, propylene glycol, titanium(IV) oxide (E171).

What Adalat LA 30 mg looks like and contents of the pack
Pink, round, convex prolonged-released tablets with laser-drilled hole, marked with “ADALAT 30” on one side.
Adalat LA 30 mg prolonged-release tablets are available in original packs of 30, 50 and 100 prolonged-release tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bayer Pharma AG
13342 Berlin, Berlin

Manufacturer
Bayer Pharma AG
Site: 51368 Leverkusen, Germany.

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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

Bayer