

(nifedipine)

Patient Information Leaflet**Read all of this leaflet carefully before you start taking this medicine**

- * Keep this leaflet. You may need to read it again.
- * If you have more questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * 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.

In this leaflet:

- 1 What Adalat LA is
- 2 Before you take Adalat LA
- 3 How to take Adalat LA
- 4 Possible side effects
- 5 How to store Adalat LA
- 6 Further information

1 What Adalat LA is

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 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 the active ingredient (nifedipine), to any other similar medicines (known as *dihydropyridines*) or to any of the other ingredients. The ingredients of Adalat LA are 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.**

Your doctor will take special care:

- * **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 breastfeeding.**
- * **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.

- **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 about any other medicines that you are taking, or took recently. This includes any products you bought 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)
- * **Cimetidine** (to treat stomach ulcers).
- * **Digoxin, diltiazem, quinidine 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).

Food and drink with Adalat LA

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.

Pregnancy and breastfeeding

If you are pregnant, think you might be pregnant or are planning a family, **tell your doctor before taking Adalat LA.**

If you need to take Adalat LA while breastfeeding, **tell your doctor before taking the tablets.**

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.

One tablet of Adalat LA 60mg contains salt (sodium). **Tell your doctor before taking the tablet.**

3 How to take Adalat LA

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

Adalat LA is not recommended for use in children and adolescents below 18 years of age because there is only limited data on the safety and efficacy in this population.

Take the tablets as prescribed by your doctor.

- * **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.
- * **Lower doses** may be prescribed for **elderly patients**
- * **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.

(nifedipine)

Patient Information Leaflet (continued)

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.

If you take too many tablets

- **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 the tablets

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.

4 Possible side effects

Like all medicines, Adalat LA can have side effects, although not everybody gets them.

If you notice:

- * hives on the body, lips, eyes or tongue
- * itching of the skin or rash
- * fast heart beat (*tachycardia*)
- * shortness of breath or difficulty breathing

- **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.

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 (*urate*)
- * 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
- * unpleasant abnormal sensation
- * inflammation of the gums, tender or swollen gums, bleeding gums

Other side effects

(*Frequency unknown*)

- * 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.
- * eye pain
- * chest pain

- * lowered white blood cell count
- * high blood sugar level
- * reduction in skin sensitivity to pain or touch
- * drowsiness or sleepiness
- * acid reflux
- * yellow discolouration of the skin (jaundice)
- * life-threatening skin reaction (toxic epidermal necrolysis)
- * allergic reaction to sunlight
- * purplish-red spots which can be felt
- * muscle / joint pain
- * shortness of breath

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Adalat LA

Keep this medicine out of the reach and sight of children.

Do not store above 30°C. Store in the original container in order to protect from light and moisture.

Protect from strong light and only remove the tablet from the blister strip when you are about to take it. Do not use after the expiry date (EXP) which is marked on both the outer carton and on each blister strip of tablets.

Do not dispose of medicines in household rubbish. Any unused Adalat LA tablets should be returned to a pharmacist (chemist) who will dispose of them properly. This helps the environment.

6 Further information**What Adalat LA 60 contains**

Each pink circular prolonged release film-coated tablet contains 60 mg of the active ingredient nifedipine and is marked "Adalat 60" on one side.

Adalat LA 60mg film-coated tablets also contain propylene glycol, cellulose acetate, hypromellose, hydroxypropylcellulose, polyethylene oxide, macrogol, magnesium stearate, sodium chloride and shellac. Titanium dioxide (E171) and iron oxide (E172) are included as colouring agents.

Each tablet contains 48mg of sodium chloride (salt) to be taken into consideration by patients on a sodium controlled diet.

Adalat LA 60mg film-coated tablet comes in calendar packs of 28 tablets.

Each tablet has the day of the week printed next to it to remind you when to take it.

What this medicine looks like and contents of the pack

Each prolonged release film-coated tablet contains 60 mg of nifedipine.

Each tablet is pink, circular and marked 'Adalat 60' on one side.

Each pack contains 28 tablets. Each tablet has the day of the week printed next to it to remind you when to take it.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufacturer:

Bayer Schering Pharma AG. Leverkusen, Germany

Revision date: 29/11/2016

Adalat is a registered trademark of Bayer AG.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0) 1527 505414 for help.

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- * **If you have had a heart attack** within the last month.
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- * **If you have unstable angina**
- * **If you are allergic** to the active ingredient (nifedipine), to any other similar medicines (known as *dihydropyridines*) or to any of the other ingredients. The ingredients of Adalat LA are listed in section 6.
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Tell your doctor:

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- * **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.

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Some medicines may affect the way Adalat LA works. **Tell your doctor** if you are taking:

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- * **Tacrolimus** (to prevent the rejection of transplanted organs).
- * **Phenobarbital** (usually used to treat insomnia or anxiety).

Food and drink with Adalat LA

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.

Pregnancy and breastfeeding

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.**

If you need to take Adalat LA while breastfeeding, **tell your doctor before taking the tablets.**

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.

One tablet of Adalat LA 60mg contains 18.3mg salt (sodium).

Tell your doctor if you are on a low-salt diet

3 How to take Adalat LA

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

Adalat LA is not recommended for use in children and adolescents below 18 years of age, because there is only limited data on the safety and efficacy in this population.

Take the tablets as prescribed by your doctor.

- * **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.
- * **Lower doses** may be prescribed for **elderly patients**
- * **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.

(nifedipine)

Patient Information Leaflet (continued)

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.

If you take too many tablets

- **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 the tablets

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.

4 Possible side effects

Like all medicines, Adalat LA can have side effects, although not everybody gets them.

If you notice:

- * hives on the body, lips, eyes or tongue
- * itching of the skin or rash
- * fast heart beat (*tachycardia*)
- * shortness of breath or difficulty breathing

- **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.

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 (*urate*)
- * 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
- * unpleasant abnormal sensation
- * inflammation of the gums, tender or swollen gums, bleeding gums

Other side effects

(*Frequency unknown*)

- * 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.
- * eye pain
- * chest pain

- * lowered white blood cell count
- * high blood sugar level
- * reduction in skin sensitivity to pain or touch
- * drowsiness or sleepiness
- * acid reflux
- * yellow discolouration of the skin (jaundice)
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- * purplish-red spots which can be felt
- * muscle / joint pain.
- * shortness of breath

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafty@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Adalat LA

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Store in the original container in order to protect from light and moisture. Only remove the tablet from the blister strip when you are about to take it. Do not use after the expiry date (EXP) which is marked on both the outer carton and on each blister strip of tablets. Do not dispose of medicines in household rubbish. Any unused Adalat LA tablets should be returned to a pharmacist (chemist) who will dispose of them properly. This helps the environment.

6 Further information**What Adalat LA 60 contains**

Each prolonged-release tablet contains 60 mg of the active ingredient nifedipine

Adalat LA also contain hypromellose, magnesium stearate, propylene, sodium chloride, red iron oxide (E172), cellulose acetate, macrogol, hydroxypropylcellulose, polyethylene, titanium dioxide (E171) and black iron oxide (E172).

What this medicine looks like and contents of the pack

Each prolonged-release tablet is a pink, circular convex tablet with 'Adalat 60' marked on one side and a laser hole on the other side. Each pack contains 28 tablets. Each tablet has the day of the week printed next to it to remind you when to take it.

The Parallel Product Authorisation Holder is:

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Repackaged by:

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Manufacturer:

Bayer Schering Pharma AG.
D-51368, Leverkusen,
Germany

Revision date: 22/11/2016

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POM

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