Package leaflet - information for the user
Adalat® Retard 20mg
prolonged-release tablets
Nifedipine

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

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1 What Adalat Retard is
Adalat Retard contains nifedipine, which belongs to a group of medicines called *calcium antagonists.*

Adalat Retard is used to treat high blood pressure or angina (*chest pain*).

For high blood pressure: Adalat Retard work 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 Retard 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 Retard
Do not take Adalat Retard:
• **If you have had a heart attack** within the last month.
• **If you get a sudden angina attack.** Adalat Retard 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 Retard are listed in section 6.
• **If you are taking rifampicin,** an antibiotic.
• **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 your blood pressure continues to rise** despite treatment *(malignant hypertension)***.**
• If you have been told to **avoid lactose**, that you have a hereditary condition called ***Lapp lactase deficiency*** or ***glucose-galactose malabsorption.***

 Tell your doctor and do not take Adalat Retard if any of these apply to you.
Your doctor will take special care:
• **If you have low blood pressure** and you were prescribed Adalat Retard 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 Retard.
• **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 Retard.
 Talk to your doctor before you take Adalat Retard 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 Retard.
• **If you have chest pains after taking your first dose** of Adalat Retard. 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 Retard may interfere with the results of certain urine tests.
• **If you are a man who has been unable to father a child** by *in vitro* fertilisation. Drugs like Adalat Retard have been shown to impair sperm function.

Other medicines and Adalat Retard
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 Retard work.

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** (antifungal 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 Retard
You can take Adalat Retard either with or without food.
Do not drink grapefruit juice or eat grapefruit while taking Adalat Retard.
Do not start taking Adalat Retard 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 Retard. 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 Retard.**
If you need to take Adalat Retard 20 mg while breastfeeding, **tell your doctor before taking the tablets.**

Driving and using machines
Adalat Retard 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 Retard

Take the tablets as prescribed by your doctor.
Adalat Retard 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.
• **To start with,** you may be given a lower strength (10mg) tablet called Adalat Retard 10mg. This allows your doctor to monitor how you are responding so that the best long term dose can be identified.
• **The usual maintenance dose** of Adalat Retard (20mg strength) is 1 tablet, every 12 hours (i.e. twice per day), but your doctor may increase or decrease the dose depending on how well your blood pressure or angina is being controlled. The maximum dose is 60mg every 24 hours. Leave at least four hours between doses.
• **Lower doses** may be prescribed for **elderly patients.**
• **If you have problems with your liver** you are likely to be given Adalat Retard 10mg, at least to begin with.
• **Swallow the tablets whole with a little water.**
• **Continue to take the tablets** for as long as your doctor has told you to.

Do not take them with grapefruit juice.

You can take Adalat Retard either with or without food.

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 as prescribed, waiting 12 hours before taking your next dose.
Do not take a double dose to make up for the missed dose.

4 Possible side effects
Like all medicines, Adalat Retard can have 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) or 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 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.

Less serious side effects
Apart from the side effects listed above, these are the other side effects of Adalat Retard tablets, 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
• unpleasant abnormal sensation
• inflammation of the gums, tender or swollen gums, bleeding gums

Other side effects
(Frequency unknown)
• 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 Retard 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 Retard
Keep this medicine out of the reach and sight of children.
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 after the expiry date 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 Retard tablets should be returned to a pharmacist (chemist) who will dispose of them properly. This helps the environment.

6 Further information

What Adalat Retard contains
Adalat Retard tablets contain the active ingredient, nifedipine. Adalat Retard tablets also contain microcrystalline cellulose, maize starch, lactose monohydrate (See section 2 Before you take Adalat Retard, Do not take Adalat Retard), polysorbate 80, magnesium stearate, hypromellose, macrogol 4000, red iron oxide (E172) and titanium dioxide (E171).

What's in the pack
Each film-coated tablet contains 20 mg of nifedipine. Each tablet is a grey-pink, circular tablet with IU on one side and a Bayer cross on the reverse.

Each pack contains 56 tablets.

Marketing authorisation holder: Bayer Ltd, The Atrium, Blackthorn Road, Dublin 18.

Manufacturer: Bayer Pharma AG, D-51368, Leverkusen, Germany

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