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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

**Package leaflet: Information for the user****Adalat® 5 mg**

Soft capsules

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 capsules are and what they are used for
2. What you need to know before you take Adalat capsules
3. How to take Adalat capsules
4. Possible side effects
5. How to store Adalat capsules
6. Contents of the pack and other information

1. What Adalat capsules are and what they are used for

Adalat capsules contain nifedipine, which belongs to a group of medicines called *calcium antagonists*.

Adalat capsules are used to treat high blood pressure, angina (*chest pain*) or a condition called *Raynaud's phenomenon* which causes discolouration (often whitening) of the fingers and toes.

For high blood pressure: Adalat capsules 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 capsules work 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.

Adalat capsules can increase the risk of serious heart problems in patients with high blood pressure or angina. Because of this, Adalat capsules are only used in these patients if no other treatments are appropriate.

For Raynaud's phenomenon: Adalat capsules work by relaxing and expanding the blood vessels in the fingers and toes. This helps ensure a good blood supply.

2. What you need to know before you take Adalat capsules

Do not take Adalat capsules:

- **If you have had a heart attack** within the last month.
- **If you get a sudden angina attack.** Adalat capsules 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 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*).

➔ **Tell your doctor and do not take Adalat capsules if any of these apply to you.**

Warnings and precautions

Talk to your doctor before taking Adalat capsules

- **If you have low blood pressure.** 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 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 capsules.
 - **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 capsules.
- ➔ **Talk to your doctor before you take Adalat capsules 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 capsules.
 - **If you have chest pains after taking your first dose** of Adalat capsules. 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 capsules 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 capsules have been shown to impair sperm function.

Other medicines and Adalat capsules

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Adalat capsules 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** (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).

Adalat capsules with food and drink

You can take Adalat capsules either with or without food.

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

Do not start taking Adalat capsules 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 capsules. 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 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 capsules but only after special consideration and agreement by your doctor.

Do not take Adalat capsules if you are breast-feeding. If you need to take Adalat capsules while breast-feeding, **tell your doctor** before taking this medicine.

Driving and using machines

Adalat capsules 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.

Adalat capsules contains Yellow orange S (E110)

May cause allergic reactions.

3. How to take Adalat capsules

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

- **The recommended starting dose is one 5 mg capsule every 8 hours.** This allows your doctor to monitor how you are responding so that the best long-term dose can be identified.
- The dose can be increased to a maximum of 20 mg every 8 hours.
- **Lower doses** may be prescribed for **older patients** or for patients who have **liver problems**.
- **Swallow the capsules whole with a little water.**
- **Continue to take the capsules** for as long as your doctor has told you to.

Do not take them with grapefruit juice.

You can take Adalat capsules either with or without food.

Use in children and adolescents: Adalat capsules are 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 capsules than you should

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

Taking too many capsules 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 capsules

Take your normal dose immediately and continue taking your capsules as prescribed, waiting 8 hours before taking your 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) 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.

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 capsules, 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)

- 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 (*hypoaesthesia*)
- 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 capsules 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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine. .

5. How to store Adalat capsules

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

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

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on both the outer carton and on each blister strip of capsules 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 capsules contain

Adalat capsules contain the active ingredient, nifedipine.

Adalat capsules also contain glycerol, purified water, saccharin sodium, peppermint oil and macrogol 400.

The capsule shell contains gelatine, glycerol, titanium dioxide (E171) and yellow orange S (E110).

What Adalat capsules look like and contents of the pack

Each oval, soft gelatine capsule is filled with a viscous yellow liquid containing 5 mg of nifedipine.

Each pack contains 90 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA

Manufacturer: Bayer Pharma AG, Leverkusen, Germany or Bayer HealthCare Manufacturing S.r.l. Garbagnate, Italy

This leaflet was last revised in April 2015.

Product licence number: PL 00010/0079

