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What *Adalat 5* is used for

- To treat vasospastic angina and chronic stable angina pectoris (chest pain).
- To treat essential hypertension (high blood pressure) and hypertensive crisis (hypertensive emergency with elevated blood pressure)
- To treat primary and secondary Raynaud's syndrome (vasospastic disorder causing discoloration of the fingers, toes, and occasionally other areas)

How *Adalat 5* works

Adalat 5 capsule contains nifedipine, which belongs to a group of medicines called calcium antagonists.

Vasospastic angina and chronic stable angina pectoris (chest pain):

Adalat 5 capsule 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.

Essential hypertension (high blood pressure) and hypertensive crisis (hypertensive emergency with elevated blood pressure):

Adalat 5 capsule 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.

Primary and secondary Raynaud's syndrome :

Adalat 5 work by relaxing and expanding the blood vessels in the fingers and toes. This helps ensure a good blood supply.

Before you use *Adalat 5*

- 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 unstable angina pectoris (chest pain) or after acute myocardial infarction (heart attack) within the first 4 weeks.
- If you are taking rifampicin, an antibiotic.

Children and adolescents

The safety and efficacy of *Adalat 5* capsule have not been established in patients aged below 18 years.

Elderly

Lower doses may be prescribed for elderly patients.

Pregnancy

Do not take *Adalat 5* capsule if you are pregnant. If you are pregnant, think you might be pregnant or are planning a family, tell your doctor before taking *Adalat 5*.

You may be able to use *Adalat 5* capsule 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 administering *Adalat 5* capsule with IV magnesium sulphate during pregnancy as there is a possibility of an excessive fall in blood pressure

Breastfeeding

Do not take *Adalat 5* capsule if you are breastfeeding. If you need to take *Adalat*

5 capsule ,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 through in vitro fertilisation, drugs like *Adalat 5* capsule have been shown to impair sperm function.

- Before you start to use it

Take special care with *Adalat 5* capsule:

- If you have low blood pressure and you were prescribed *Adalat 5* capsule 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 a liver disease that prevents your liver from working properly.
- Treatment with immediate release nifedipine may induce an exaggerated fall in blood pressure with abnormally rapid heartbeat, which could result in cardiovascular complications.

As with other vasoactive substances, angina pectoris (chest pain) may occur with immediate release nifedipine, especially at the start of the treatment.

In patients suffering from angina pectoris (chest pain) an increase in frequency, duration and severity of angina pectoris attacks may occur, especially at the start of the treatment.

The occurrence of myocardial infarction (heart attack) has been described in isolated cases,although it was not possible to distinguish this from the natural course of the underlying disease.

- 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 5* capsule 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 5*

- How much to use

Always take *Adalat 5* capsule exactly as your doctor has told you.

Dose for chronic stable angina pectoris: the usual dose is 1 capsule, 3 times daily.

Dose for vasospastic angina pectoris: the usual dose is 1 capsule, 3 times daily.

Dose for hypertension: the usual dose is 1 capsule, 3 times daily.

Dose for hypertensive crisis: the usual dose is 1 capsule as a oral single dose.

Dose for Raynaud's syndrome: the usual dose is 1 capsule, 3 times daily.

Starting dose should be nifedipine 5 mg preferably.

Swallow the capsules whole.

Take your capsules with a glass of water. Do not take them with grapefruit juice. Grapefruit juice is known to increase the blood levels of the active ingredient of *Adalat 5* capsule, nifedipine. This effect can last for at least 3 days.

- When to use it

You can take *Adalat 5* capsule with or without food.

Patients taking 20 mg unit doses of *Adalat 5* capsule should allow an interval of at least 2 hours between doses.

- How long to use it

Continue taking *Adalat 5* capsule for as long as your doctor recommends.

- If you forget to use it

Take your normal dose immediately and continue taking your capsules at the usual time of day. 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 5*.

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 5* capsule to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Adalat 5 capsule 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 5* capsule 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 we list possible side effects by how common they are.

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)

- 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 5- Storage

Keep out of the reach and sight of children.

Do not use *Adalat 5* capsule 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 5 mg capsule: Orange softgel capsule, 3 minims oval

- Ingredients

- Active ingredient

One 5 mg capsules contains 5 mg nifedipine

- Inactive ingredients

- gelatine,
- glycerol,
- polyethylene

- glycol 400,
- peppermint oil,
- purified water,
- saccharin sodium,
- sunset yellow FCF (E 110/C.I. 15985),
- titanium dioxide (E 171/C.I.77891).

- MAL number:

MAL19880105A

Bulk manufactured by:

R.P. Scherer GmbH & Co KG,
Eberbach/Baden, Germany

Quality control and final release:

Bayer Pharma AG
D-51368 Leverkusen, Germany

Product Registration Holder

Bayer Co. (Malaysia) Sdn Bhd
Unit T1-14, Tower 1, Jaya 33,
No 3, Jalan Semangat,
Seksyen 13,
46200 Petaling Jaya, Selangor

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26/09/2014

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