SCHEDULING STATUS: **S3**

PROPRIETARY NAMES AND PHARMACEUTICAL FORMS:

ADALAT® XL 20 tablets
Controlled-release tablet, Nifedipine 20 mg per tablet
ADALAT® XL 30 tablets
Controlled-release tablet, Nifedipine 30 mg per tablet
ADALAT® XL 60 tablets
Controlled-release tablet, Nifedipine 60 mg per tablet

Read all of this leaflet carefully before you start taking ADALAT XL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

ADALAT XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours**.**

1. WHAT ADALAT XL CONTAINS:

- The active substance is nifedipine. ADALAT XL 20 contains 20 mg nifedipine, ADALAT XL 30 contains 30 mg nifedipine and ADALAT XL 60 contains 60 mg nifedipine.
- The other ingredients are: cellulose acetate, ferric(III) oxide (E 172), hydroxypropyl cellulose, macrogol 3350, macrogol 200000, macrogol 5 million, magnesium stearate, hydroxypropyl methylcellulose, sodium chloride, propylene glycol, titanium(IV) oxide (E 171).

2. WHAT ADALAT XL IS USED FOR:

ADALAT XL is used to treat:

- Chronic stable angina (chest pain).
- Mild to moderate hypertension (high blood pressure).

3. BEFORE YOU TAKE ADALAT XL:

3.1 Do not take ADALAT XL if you:

- are hypersensitive or allergic to nifedipine or to any of the other ingredients of ADALAT XL;
- are in cardiovascular shock (a collapse caused by a heart problem, during which you became breathless, pale and had a cold sweat and dry mouth) or have had it previously;
- have severe narrowing of the valve leading from the heart to the main artery (severe aortic stenosis);
- have unstable angina pectoris (chest pain);
- have suffered an acute heart attack in the last 4 weeks;
- have severe narrowing or blockage of the gastrointestinal tract (oesophagus, stomach, intestines);
- have inflammatory bowel disease;
- have liver disease;

- are taking rifampicin (anti- tuberculosis medicine) at the same time;
- are pregnant or breastfeeding;
- have a Kock pouch (ileostomy after proctocolectomy) - a surgically constructed intestinal reservoir with an opening through the abdominal wall of your gut.

3.2 Take special care with ADALAT XL:

- if you have low blood pressure.
- if you have very severe heart weakness (decompensated heart failure).
- if you
  - are undergoing dialysis; and
  - also have high blood pressure despite treatment (malignant hypertension); and
  - also have decreased blood volume (hypovolaemia)

  as widening of the blood vessels (vasodilation) caused by ADALAT XL can cause substantial fall in your blood pressure.

- if you suffer from diabetes; ADALAT XL may cause an increase in your blood glucose (sugar) levels.
- tell your doctor or healthcare professional before being given an intravenous magnesium sulphate injection, that you are taking ADALAT XL.
- 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.
- tell your doctor if you experience bezoars (tightly packed collection of partially digested or undigested material not able to exit the stomach) as they can occur and may have to be removed by surgery.

3.3 Taking ADALAT XL with food and drink:

Taking ADALAT XL with grapefruit may result in an increased blood pressure lowering effect. This may lead to dizziness or fainting. The blood pressure lowering effect may last for at least 3 days after the last ingestion of grapefruit.

You can take ADALAT XL independently of meal times. Swallow the tablets whole with a glass of fluid. **Do not chew, bite or break the tablet.**

3.4 Pregnancy and breastfeeding:

ADALAT XL should not be used during pregnancy, as it will harm your baby.
You should not breastfeed your baby if you are taking ADALAT XL.

3.5 Driving and using machinery:

ADALAT XL may reduce your reaction time; and thus your ability to drive and to operate machinery. This applies particularly at the start of treatment, when the dose is increased, when medication is changed and when taken in conjunction with alcohol.

3.6 Using other medicines with ADALAT XL:

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

Medicines that may strengthen the blood pressure lowering effect of ADALAT XL:

- tricyclic antidepressants (medicines used to treat depression).
- beta blockers (medicines used to treat high blood pressure and coronary heart disease).

- nitrates (medicines used to treat coronary heart disease).
- cimetidine (medicine used to treat gastric and intestinal ulcers).
- diltiazem (used to treat high blood pressure and coronary heart disease).
- quinupristin/dalfopristin (antibiotics).
- valproic acid (medicine to treat epilepsy).
- erythromycin (antibiotic).
- protease inhibitors such as indinavir, ritonavir or saquinavir (medicines to treat certain viral infections).
- antifungals such as ketoconazole, itraconazole or fluconazole (medicines to treat fungal infections.
- fluoxetine (antidepressant).

Your blood pressure should be monitored regularly as simultaneous treatment of ADALAT XL and the above mentioned medicines may lead to an extreme reduction in blood pressure and possible heart failure.

Medicines that may decrease the blood pressure lowering effect of ADALAT XL:

- phenytoin (medicine to treat epilepsy).
- carbamazepine or phenobarbital (medicine to treat epilepsy)
- rifampicin (a medicine used to treat tuberculosis)

ADALAT XL may affect the action of the following medicines:

- quinidine (medicine to treat heart rhythm disturbances). Your blood levels of quinidine should be monitored if you use it together with ADALAT XL.
- digoxin (medicine to treat heart diseases).
- theophylline (medicine to treat respiratory diseases like asthma).
- tacrolimus (medicine to prevent transplant rejection, for example liver or kidney transplant).

Using these medicines together with ADALAT XL may increase your blood levels of the above medicines; the doctor will monitor these levels to decide whether to continue treatment.
Please note that this information may also apply to medicines used recently.

4. HOW TO TAKE ADALAT XL:

Do not share medicines that are prescribed for you with any other person.

Always take ADALAT XL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Grapefruit juice is to be avoided.

You should swallow the tablets whole with a glass of fluid; under no circumstances must you bite, chew or break them up. The tablets should be taken at approximately 24 hour intervals, i.e. at the same time each day, preferably during the morning. ADALAT XL need not be taken with meals.

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.

Your doctor will decide on the duration of your treatment. Your doctor will decide which dose you should take and to increase or decrease the dose.

If you have the impression that the effect of ADALAT XL is too strong or too weak for you, tell your doctor or pharmacist.

If you take more ADALAT XL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 of the lungs due to fluid (pulmonary oedema), low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take ADALAT XL:

Take your ADALAT XL tablet as soon as you remember. Take your usual dose at the usual time on the following day. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ADALAT XL is stopped:

You should always consult your doctor before you decide to interrupt the course of treatment or to stop taking ADALAT XL altogether.

5. POSSIBLE SIDE EFFECTS:

ADALAT XL can have side effects.

Not all side effects reported for ADALAT XL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADALAT XL, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking ADALAT XL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the face, lips, tongue and throat which may be life-threatening).
- other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may be life-threatening).
- shortness of breath or difficulty breathing.
- 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).

These are all serious side effects. You may need urgent medical attention.

Other frequent side effects include:

If any of these side-effects continue, are severe or bother you, tell your doctor or pharmacist:

- headache.
- eye pain.
- flushing.
- general feeling of being unwell.
- constipation.
- swelling, particularly of the ankles and legs.

Less frequent side effects include:

- sleep disorders, anxiety or nervousness.
- sensation of spinning or whirling motion *(vertigo),* migraine, dizziness, trembling or drowsiness (somnolence).
- blurred vision.
- irregular heartbeat (palpitations).
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion) or fainting.
- nose bleeds or nasal congestion.
- stomach pain *(abdominal pain),* dry mouth, indigestion or upset stomach, wind *(flatulence)* or feeling sick *(nausea),* heartburn (gastrooesophageal reflux).
- temporary increase in certain liver enzymes.
- reddening of the skin.
- muscle cramps, muscle pain.
- joint swelling, joint pain.
- increase in the need to pass water (urinate) or painful or difficult urination.
- inability to achieve or maintain an erection *(impotence).*
- unspecific pain or chills.
- pins and needles.
- inflammation of the gums, tender or swollen gums, bleeding gums.
- lazy eye (amblyopia).
- chest pain (angina pectoris).
- small, raised areas of bleeding in the skin (palpable purpura).
- a more severe decrease in a specific class of white blood cell (agranulocytosis).
- increased blood sugar (hyperglycaemia).
- decreased skin sensitivity (hypoaesthesia).
- difficulty in breathing (dyspnoea).
- difficulty swallowing.
- abdominal pain, caused by obstruction of the gut or ulcers in the gut.
- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal; vomiting.
- yellowing of the whites of the eyes or skin (jaundice).
- sensitivity to light (photosensitivity allergic reaction).
- the abnormal development of large mammary glands in males resulting in breast enlargement (gynaecomastia).

All of these symptoms usually go away when treatment with ADALAT XL is stopped.
Tell your doctor if any side effect gets serious, or if you get any effects not listed in this leaflet.

6. STORING AND DISPOSING OF ADALAT XL:

- Not to be removed from the outer carton until required for use.
- Store all medicines out of reach of children.
- Return unused or expired medicines to your pharmacist for safe disposal.
- Store at or below 30 °C. Protect from light and moisture.

7. PRESENTATION OF ADALAT XL:

Blister packs composed of PP/Alu foil, PVC/ PVDC foil or PA/Al/PVC foil backed with aluminium foil containing 28 or 30 tablets packed in a cardboard carton.

8. IDENTIFICATION OF ADALAT XL:

Round, convex, pink coated tablet with a laser hole on one side and marked in black printed text:

ADALAT 20, ADALAT 30 or ADALAT 60.

9. REGISTRATION NUMBERS:

ADALAT XL 20: A39/7.1/0634
ADALAT XL 30: Y/7.1/314
ADALAT XL 60: Y/7.1/315

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
Isando
1609

11. DATE OF PUBLICATION:

Registration dates:
ADALAT XL 20:09/12/2008
ADALAT XL 30:01/10/1992
ADALAT XL 60:01/10/1992

Last publication date: 29 July 2016

® = Registered Trademark of Bayer AG, Germany