

## **Package leaflet: Information for the user**

**Adanif<sup>®</sup> XL 30mg Tablets**

**Adanif<sup>®</sup> XL 60mg Tablets**

nifedipine

**Read all of this leaflet carefully before you start using 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.

Your medicine is called Adanif XL 30mg or 60mg Tablets (They will be called Adanif XL Tablets throughout this leaflet.)

### **What is in this leaflet:**

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

## **1. What Adanif XL Tablets are and what they are used for**

Adanif XL Tablets contains nifedipine, which belongs to a group of medicines called calcium antagonists.

Adanif XL Tablets are used to treat high blood pressure or angina (chest pain).

For high blood pressure: Adanif XL Tablets 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: Adanif XL Tablets 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. What you need to know before you take Adanif XL Tablets

### Do not take Adanif XL Tablets

- if you have had a heart attack within the last month.
- if you get a sudden angina attack. Adanif XL Tablets will not help relieve symptoms of angina quickly
- if you have unstable angina;
- if you are allergic to nifedipine or 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 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 Adanif XL if any of these apply to you**

### Warnings and precautions

Talk to your doctor or pharmacist before taking Adanif XL Tablets

- if you have low blood pressure and you were prescribed Adanif XL Tablets for your angina.
- if 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 need to take Adanif XL Tablets, you should stop breastfeeding before you start to take this medicine.
- 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 Adanif XL Tablets.
- 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 Adanif XL Tablets.

→Talk to your doctor before you take Adanif XL Tablets 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 Adanif XL Tablets.
- if you have chest pains after taking your first dose of Adanif XL Tablets. 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. Adanif XL Tablets 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 Adanif XL Tablets have been shown to impair sperm function.

### **Other medicines and Adanif XL Tablets**

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

Some medicines may affect the way Adanif XL Tablets 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).

### **Adanif XL Tablets with food and drink**

You can take Adanif XL Tablets with or without food.

Do not drink grapefruit juice or eat grapefruit while taking Adanif XL Tablets.

Do not start taking Adanif XL Tablets 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 Adanif XL Tablets. 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 Adanif XL Tablets but only after special consideration and agreement by your doctor.

Do not take Adanif XL Tablets if you are breast-feeding. If you need to take Adanif XL Tablets, you should stop breast-feeding before you start taking this medicine.

#### **Driving and using machines**

Adanif XL Tablets 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.

**Adanif XL Tablets contain lactose monohydrate** – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product .

### **3. How to take Adanif XL Tablets**

Adanif XL Tablets are specially formulated so that you only have to take one dose each day.

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

The recommended dose is :

#### **Use in adults including the elderly**

- **Dose for high blood pressure:** The usual starting dose is one 30mg tablet taken once a day.
- **Dose for angina:** the dose depends on your individual requirements. Your doctor will decide how much you should take.
- **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 at about 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 Adanif XL Tablets with or without food.

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.

#### **Use in children and adolescents**

- Adanif XL Tablets 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 Adanif XL Tablets than you should**

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

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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 Adanif XL 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 a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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#### **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), 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 (frequency not known) 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 Adanif XL 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 1000 people*)

- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums

**Other side effects**

**Not known** (*frequency cannot be estimated from the available data*)

- 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
- 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
- depression

All of these symptoms usually go away when treatment with Adanif XL Tablets 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 Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Adanif XL Tablets

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package to protect from light.

Do not use this medicine if you notice any damage or discoloration of the tablets. Return them to your pharmacist.

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 Adanif XL Tablets contains:

- The active substance is nifedipine.
- The other ingredients are: tablet core - talc (E533b), povidone (E1201), hypromellose (E464) and carbomer 974P, lactose monohydrate, silica colloidal anhydrous and magnesium stearate; coating - Eudragit "E", titanium dioxide (E171), ferric oxide (E172), talc (E533b), magnesium stearate, hypromellose and macrogol 4000.

### What Adanif XL Tablets look like and contents of the pack

Adanif XL 30mg and 60mg Tablets: round tablets with a pale red colour.

Each carton of Adanif XL Tablets contains 28 tablets.

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For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

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