

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adanif® XL 30mg Tablets Adanif® 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Your medicine is called Adanif XL 30mg or 60mg Tablets; they contain nifedipine as the active ingredient. (They will be called Adanif XL Tablets throughout this leaflet.)

What this medicine does

Your doctor has prescribed Adanif XL Tablets for:

- High blood pressure (hypertension): nifedipine works by widening blood vessels, allowing blood to flow more freely, thus reducing the strain on your heart.
- Angina (lack of oxygen to the muscles of the heart leading to pain in the centre of the chest radiating over the left side of the body, up the neck and down the left arm). Nifedipine reduces the frequency of angina attacks by opening the blood vessels (arteries) of the heart allowing more oxygen and blood to reach the muscles of the heart.

Adanif XL Tablets contain nifedipine, a medicine known as a selective calcium channel blocker.



2. What you need to know before you take Adanif XL Tablets

Do not take Adanif XL Tablets

- if you are allergic (hypersensitive) to nifedipine or other similar medicines such as amlodipine and felodipine or any of the other ingredients of Adanif XL Tablets (see Section 6);
- if you are breast-feeding;
- if you have any other heart conditions such as:
 - your heart is not pumping blood properly, a condition known as cardiogenic shock;
 - you have a narrowing of the main artery (the aorta) from the heart to the rest of the body. This condition is known as an aortic stenosis;
 - unstable angina;
 - if you have had a heart attack within the past month;
- if you are having an acute angina attack – DO NOT TAKE Adanif XL Tablets when an angina attack occurs;
- if your blood pressure continues rising despite treatment;
- to prevent a heart attack;
- if you have liver problems;
- if you suffer with any narrowing or obstruction of your intestines (guts) or oesophagus (gullet);
- if you suffer from Crohn's disease or any disease that causes swelling or inflammation of the intestines (gut);
- if you have an ileostomy bag (a special bag, also called a Kock pouch, attached to the intestines to collect waste from the body);
- if you are taking rifampicin, an antibiotic. See "Using other medicines" section.

Talk to your doctor, pharmacist or nurse if any of the following apply to you:

- if you already have low or very low blood pressure (a systolic pressure of less than 90mmHg). Symptoms of this may include feeling dizzy or passing out when you stand up;
- if you have a heart condition or you have been told your heart is failing;
- if you are diabetic (high levels of sugar in the blood);
- if you are having kidney dialysis;
- if you are having an x-ray procedure that uses a barium meal or contrast (a special solution used for diagnosing patients having certain x-ray procedures);
- if you have any urine tests. Nifedipine may increase the amounts of vanillylmandelic acid (a waste product excreted in your water) if measured using certain methods.

Tell your doctor or pharmacist if you have any of the above.

Using other medicines

Make sure your doctor knows if you are taking a medicine listed here:

Medicines that may **decrease** the levels and effects of nifedipine are:

- **Rifampicin** an antibiotic used for legionnaire's disease and leprosy.
- **Phenytoin** used to treat epilepsy and pain around the face.
- **Carbamazepine** used to treat epilepsy.
- **Phenobarbital** used to help you sleep and to treat some types of epilepsy.

Medicines that may **increase** the levels and effects of nifedipine are:

- **Macrolide antibiotics** such as erythromycin, clarithromycin and azithromycin used for many types of infections, such as tonsillitis, bronchitis and skin infections.
- **Anti-HIV Protease Inhibitors** such as ritonavir, indinavir and nelfinavir used to treat HIV.
- **Azole anti-fungals** (anti-mycolytics) such as ketoconazole, itraconazole and fluconazole used for many types of fungal infections.
- **Fluoxetine and Nefazodone** used to treat depression and obsessive-compulsive disorders.
- **Quinupristin and Dalpofristin** antibiotics used for various skin and blood infections.
- **Cisapride** used for night-time heartburn.
- **Valproic acid** used to treat epilepsy.
- **Cimetidine** used to treat stomach ulcers and for reducing the amount of stomach acid.
- **Diltiazem** used for angina and high blood pressure.

Other medicines that are affected by nifedipine are:

- **Beta-blocking medicines** such as propranolol or atenolol used to help prevent heart attacks and an irregular heartbeat or to treat high blood pressure and angina. These medicines may decrease blood pressure too much and can lead to dizziness especially when you go from a sitting to standing position or a lying to sitting position.
- **Digoxin** used for heart failure and abnormal heartbeats. Nifedipine reduces clearance of digoxin so your doctor may reduce the dose of digoxin to prevent overdosing.
- **Quinidine** used to treat increased and abnormal heartbeats. The levels of quinidine are reduced by nifedipine, regardless of dose of quinidine taken. Blood pressure and levels of quinidine should be monitored.
- **Tacrolimus** used to suppress the immune system and prevent organ rejection in transplant patients. Nifedipine increases levels of tacrolimus so a reduction in dose may be necessary.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Adanif XL Tablets with food and drink Do not take Adanif XL Tablets within 3 days of having anything containing grapefruit.

- Do not take Adanif XL tablets with grapefruit or grapefruit juice because it may increase the levels of nifedipine leading to an increased effect or even overdose.
- Swallow the tablets whole with a glass of water, with or without food.

Pregnancy and breast-feeding

- Speak to your doctor or pharmacist for advice before taking Adanif XL Tablets, if you are pregnant, thinking of getting pregnant or breast-feeding.
- Speak to your doctor or pharmacist for advice before taking Adanif XL Tablets, especially if you are having magnesium sulphate injections (used for magnesium deficiency).
- Nifedipine may affect male fertility, your fertility will return once you stop taking the drug. If you are trying to father a child without success, tell your doctor that you are taking nifedipine.

Driving and using machines

- Adanif XL Tablets may decrease your ability to drive or operate machinery safely.
- Do not drive or operate machines if you are affected.

Important information about some of the ingredients in Adanif XL Tablets

- 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 medicine.



3. How to take Adanif XL Tablets

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 :

ALWAYS: swallow the tablet whole, with a glass of water; at about the same time each day.

DO NOT bite, chew or break-up the tablet.

Do not take within 3 days of having grapefruit or grapefruit juice.

Adults including the elderly

- The usual starting dose is one 30mg tablet taken once a day.
- The dose may be increased to a maximum of 90mg once daily depending on your response to the drug.
- Take at about the same time each day, preferably in the morning.
- If you are already taking other nifedipine containing medicines your doctor may have switched you to a long-acting formulation, such as Adanif XL Tablets. If this is the case the starting dose above should be used.

Children

- 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.

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.

If you take more Adanif XL Tablets than you should

- If you take more Adanif XL Tablets than your doctor has prescribed, or you think a child has accidentally swallowed any, call your doctor or go to the nearest hospital emergency department **immediately**. Take the medicine or this leaflet with you to show the doctor.

If you forget to take Adanif XL Tablets

- **Do not** take double the amount to make up for a forgotten dose.
- Take the next dose immediately.
- Continue taking your tablets at your usual time of day; but wait at least 12 hours before taking your next dose.

If you stop using Adanif XL Tablets

- **Do not** stop taking Adanif XL Tablets suddenly.
- Speak to your doctor before you stop taking Adanif XL Tablets.

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



4. Possible Side Effects

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

Take immediate action if you have any of the following side effects:

severe allergic reaction which may include yellowing of the skin or eyes (jaundice); severe skin disorder which causes the outer layer of skin to detach; raised, purple-red spotting on the skin; itching, reddening or scaling of the skin; a red and lumpy skin rash; difficulty breathing; swelling of face, mouth, lips or eyelids; unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

Common (up to 1 in 10 people)

- headache;
- flushing due to widening of the blood vessels (vasodilation);
- constipation;
- swelling (oedema), sometimes of the hands, feet and/or ankles;
- generally feeling unwell.

Uncommon (up to 1 in 100 people)

- feeling anxious;
- problems sleeping;
- migraines;
- trembling or involuntary movements;
- changes in your vision;
- pain of the abdomen, stomach, intestines (gut) or generally all over;
- dizziness;
- low blood pressure (leading to fainting or feeling dizzy), especially when you stand-up if sitting or sit up after lying down;
- fainting or loss of consciousness;
- increased heart rate;
- an irregular and/or forceful heart beat (palpitations);
- nosebleeds;
- blocked nose or congestion;
- chills;
- dry mouth;
- indigestion;
- wind (flatulence);
- feeling sick (nausea);
- changes to the levels of some liver enzymes;
- muscle cramps;
- swelling of the joints;
- giddiness or feeling unbalanced (vertigo);

- redness or flushing of the skin;
- difficulty achieving or maintaining an erection (impotence);
- passing an increased amount of water or pain when urinating.

Rare (up to 1 in 1000 people)

- change in sensitivity to touch (either increased, decreased or loss), tingling, pins and needles and very sensitive skin;
- itching, rash, swelling or blisters (hives);
- swelling or enlargement of the gums.

Other side effects (where the frequency is not known)

- breathlessness or difficulty breathing;
- shortness of breath
- being sick (vomiting);
- formation of a mass of foreign material in the stomach or intestines (gut);
- blockage or obstruction of the intestines (gut);
- ulceration of the intestines (gut);
- difficulty swallowing or keeping down food or drink;
- lesions or ulcers in the throat, mouth and skin;
- low resistance to infections due to a reduced number of white blood cells (leucopenia);
- high levels of sugar in your blood (hyperglycaemia) that makes you feel thirsty or need to urinate more often;
- reduced sense of touch or sensation;
- feeling sleepy or drowsy;
- eye pain;
- chest pain;
- muscle or joint pain.

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 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. 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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