

PATIENT INFORMATION LEAFLET

VALNI XL 30MG & 60MG PROLONGED RELEASE TABLETS

Nifedipine

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist (See section 4).

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1. WHAT VALNI XL IS AND WHAT IT IS USED FOR

VALNI XL Prolonged Release Tablets contain nifedipine which belongs to a group of medicines called calcium-channel blockers that act on the cardiovascular system (the heart and blood vessels). VALNI XL has been prescribed by your doctor to treat your high blood pressure or to reduce the frequency of your anginal attacks. They are called prolonged release tablets because they are manufactured in a way that allows the nifedipine to be released and slowly absorbed by your body over a period of several hours.

In high blood pressure, nifedipine works by widening the blood vessels. This creates less resistance to the blood flow, and results in lower blood pressure, which in turn reduces the strain on your heart.

In angina, nifedipine works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina (chest pains) occurring when extra strain is placed upon the heart.

2. BEFORE YOU TAKE VALNI XL

Do not take VALNI XL:

- if you are allergic to nifedipine, other calcium-channel blockers (e.g. verapamil, diltiazem or felodipine) or any of the other ingredients of VALNI XL
- if you have been told that you have a narrowing (stenosis) of the aortic valve in your heart
- if you have experienced a collapse which was caused by a heart problem (cardiogenic shock)
- if the severity or frequency of your angina has rapidly worsened over a matter of hours or days
- to treat an angina attack as it occurs, but rather to reduce the frequency of the angina you experience over time
- if you suffer from inflammation of the bowel or intestines (such as Crohn's disease), oesophageal (gullet) obstruction or have in the past had an obstruction or narrowing of the intestine
- if you have a liver disease
- if you have had a heart attack during the last month or to treat a heart attack
- if you are taking the antibiotic rifampicin (used to treat tuberculosis)
- if your blood pressure continues to rise despite treatment (malignant hypertension)
- if you have a 'Kock pouch' (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

Take special care with VALNI XL:

It is important that you tell your doctor if any of the following applies to you.

- if you suffer from low blood pressure
- if you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve)
- if you are pregnant
- if you are breastfeeding. If you need to take VALNI XL, you should stop breastfeeding before you start to take this medicine.
- if you experience chest pains when you **first** start taking VALNI XL, contact your doctor **immediately**
- if you notice increased breathlessness and swelling of the ankles
- if you are diabetic, the treatment for your diabetes may need to be adjusted
- if you are receiving kidney dialysis and have very high blood pressure with low blood volume
- if you are taking other drugs to treat high blood pressure (e.g. beta-blockers). If you are changing from a beta-blocker to nifedipine, you should gradually reduce your beta-blocker after discussion with your doctor

- if you have to give a urine sample, have an x-ray or undergo surgery

Your doctor may, under certain conditions, think it necessary to keep you on VALNI XL whilst you are pregnant. If this is the case particular care must be taken if you are also receiving magnesium sulfate injections.

Taking other medicines:

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

In particular, tell your doctor if you are taking:

- other drugs to treat high blood pressure
- cimetidine, to treat stomach ulcers
- the medicines digoxin, diltiazem, quinidine, or beta-blockers, used to treat heart conditions
- the anti-epileptic drug phenytoin
- the antibiotic rifampicin and combination treatment quinupristin/dalfopristin
- cisapride, a drug used to treat reduced movements of the gullet and stomach

The effect of the following drugs on VALNI XL is uncertain. Therefore, as an additional precaution, please tell your doctor if you are taking:

- the antibiotic erythromycin,
- the antifungal drugs ketoconazole, itraconazole or fluconazole
- the HIV protease inhibitors indinavir, nelfinavir, zidovudine, zalcitabine, zalcitabine or amprenavir
- the antidepressant drugs fluoxetine and nefazodone
- tacrolimus, an immunosuppressant used to prevent the rejection of transplant organs
- carbamazepine and valproic acid, used for the treatment of epilepsy
- the barbiturate phenobarbital, used primarily to treat insomnia and anxiety

The following drugs do not interact with VALNI XL: aspirin, benazepril, candesartan cilexetil, orlistat, debrisoquine, doxazosin, irbesartan, omeprazole, pantoprazole, ranitidine, rosiglitazone and triamterene hydrochlorothiazide.

VALNI XL with food and drink:

Do not drink grapefruit juice or eat grapefruit whilst taking VALNI XL because grapefruit juice can increase the blood levels of nifedipine.

Do not start taking VALNI XL within 3 days of drinking grapefruit juice or eating grapefruit. The effects of this can last for at least 3 days so it is important to tell your doctor if you have had grapefruit juice or ate grapefruit during this time.

Pregnancy and breast-feeding:

Tell your doctor if you are pregnant, think you might be pregnant or are planning a family.

You may be able to use VALNI XL, but only after special consideration and agreement by your doctor. **Do not take VALNI XL if you are breast feeding.** If you need to take VALNI XL, you should stop breastfeeding before you start taking the tablets.

Drugs like VALNI XL have been shown in laboratory experiments to impair sperm function. If you are male and have been unsuccessful in fathering a child please consult your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

It is possible that you may react to VALNI XL. Reactions can vary in intensity from individual to individual and may affect your concentration. VALNI XL may make you feel dizzy, faint, extremely tired or have visual disturbances. If you are unable to concentrate or remain alert after taking VALNI XL, then **do not drive or operate machinery** or perform any activity for which you need to be attentive. This applies particularly at the start of treatment, on changing medication or in combination with alcohol.

Important information about some of the ingredients of VALNI XL:

VALNI XL contains 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 VALNI XL

Always take VALNI XL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

VALNI XL is specially formulated so that you only have to take your tablets **once a day**, preferably in the morning. Your tablet must be swallowed whole with a glass of water and **not** with grapefruit juice.

Do not break, bite or chew your tablets. VALNI XL may be taken with or without food.

The usual adult dose for treating high blood pressure or preventing angina is 30mg or 60mg once a day. Your doctor may decide to increase your dose to a maximum of 90mg of nifedipine once a day.

If you are elderly, lower doses of this medicine may be prescribed by your doctor.

Do **not** stop taking your medicine until your doctor tells you.

Children and adolescents under 18 years of age must **not** take this medicine.

If you take more VALNI XL than you should:

If you take more VALNI XL than you should, immediately contact your doctor or pharmacist. Elimination of the product and the restoration of stable cardiovascular conditions may be needed. If you take too much nifedipine low blood pressure (hypotension) can occur, which can be recognised from symptoms like dizziness, nausea, vomiting, drowsiness, confusion, lethargy, flushing, a lack of oxygen (hypoxia), headache or red spots on the face. Eventually, unconsciousness can occur.

Increased or decreased heart rates are also a symptom of overdose. In the event of overdose it is recommended to lay the patient down with elevated legs, for instance by using some pillows.

If you forget to take VALNI XL:

Do not take a double dose to make up for a forgotten dose.

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.

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

If you stop taking VALNI XL:

If you suddenly stop using this medicine, the symptoms that you had before you started taking this medicine can come back.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, VALNI XL can cause side effects, although not everyone gets them. **If you experience any of the following side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department:**

- 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 or difficulty breathing
- mild to moderate allergic reactions
- itching (possibly severe), a rash or hives.
- 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*)

Apart from the side effects listed above, these are the other side effects of VALNI XL, 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*) • migraine • a dry mouth • indigestion or upset stomach • wind (*flatulence*) • feeling sick (*nausea*) • leg pain, leg cramps, muscle cramps • joint swelling • sleep disorders • anxiety or nervousness • reddening of the skin • nose bleeds • nasal congestion • sensation of spinning or whirling motion (*vertigo*) • dizziness • itching, • trembling • increase in the need to pass water (*urinate*) especially at night • painful or difficult urination • inability to achieve or maintain an erection (*impotence*) • blurred vision • temporary increase in certain liver enzymes • diarrhoea

Rare side effects – these may affect up to 1 in 1,000 people

- pins and needles • swelling of the face, • loss of appetite (anorexia), • belching, • inflammation of

the gums, tender or swollen gums, bleeding gums • increased sensitivity, particularly in the skin, (hyperaesthesia) • sweating, • problems with your gut, • fever • mood changes • problems with your joints that may be painful

Other side effects – frequency unknown

- stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal • difficulty in swallowing • inflammation of the gullet, • 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*) • weight loss • 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-associated with liver function*) • muscle pain • joint pain • sensitivity to light (*photosensitivity allergic reaction*). • increased blood sugar (*hyperglycaemia*) • small, raised areas of bleeding in the skin (*palpable purpura*), shortness of breath.

A slight development in breast tissue has also been reported in older men on long term therapy. Because of the nature of coronary artery disease, heart attacks have occurred in patients treated with the active ingredient, nifedipine. It has not been shown that these heart attacks were due to treatment with nifedipine.

All of these symptoms usually go away when treatment with VALNI XL 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 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 VALNI XL

- **Keep out of the sight and reach of children.**
- Do not store above 25°C. Keep the blister in the outer carton.
- Do not use VALNI XL after the expiry date which is stated on the blister and carton.
- 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What VALNI XL contains:

- The active substance is nifedipine.
- The other ingredients are povidone K30, lactose monohydrate, talc, hypromellose (E464), magnesium stearate, carbomer 974P, colloidal anhydrous silica, macrogol 4000, dimethylaminoethyl methacrylate-butyl methacrylate-methyl methacrylate copolymer, red iron oxide (E172) and titanium dioxide (E171).

What VALNI XL look like and the contents of the pack:

Valni XL 30mg and 60 mg Prolonged Release Tablets are pale red with a round and biconvex shape, marked on one side with “30” or “60” respectively. They are available in calendar blister packs of 28 tablets.

The Marketing Authorisation Holder is:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

The Manufacturer is:

Zentiva Pharma UK Limited, Office 136-152, Austen House, Station View Units A-J, Guildford, GU1 4AR, UK

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