

PATIENT INFORMATION LEAFLET

Valni 20 Retard

(Nifedipine 20mg Modified Release Tablets)

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet:

1. What Valni is and what it is used for
2. What you need to know before you take Valni
3. How to take Valni
4. Possible side effects
5. How to store Valni
6. Contents of the pack and other information

1 What Valni is and what it is used for

The active ingredient in Valni is Nifedipine which is one of a group of medicines known as calcium channel blockers. These work by opening up the blood vessels and increasing the flow of blood to them.

Valni (Nifedipine 20mg modified release tablets referred to as Valni throughout this leaflet) is used:

- To treat high blood pressure (hypertension)
 - To prevent attacks of chest pain (angina) diagnosed by your doctor as chronic stable angina
- Angina is caused by a narrowing of the arteries in the heart muscle. Chronic stable angina is a pattern of attacks of chest pain that are predictable and happen under certain conditions such as after exercise, stress or in cold weather.

2 What you need to know before you take Valni

Do not take Valni if:

- You are allergic (hypersensitive) to Nifedipine or any of the other ingredients of this medicine (See Section 6 "Contents of the pack and other information")
- You are allergic (hypersensitive) to other similar medicines (known as dihydropyridine) such as Nicardipine, Amlodipine, Felodipine, Isradipine, Lacidipine or Nimodipine
- You suffer from narrowing of the valve in your heart (aortic stenosis)
- You have a sudden attack of chest pain (angina) or chest pain even at rest, which increases in severity (unstable angina)
- You have suffered a heart attack within the last month (acute myocardial infarction)
- You have a history of heart attacks (myocardial infarction)
- Your heart is damaged so that it is unable to supply sufficient blood to the body (cardiogenic shock)
- You are taking Rifampicin, medicine used to treat bacterial infections (See "Other medicines and Valni" section)
- Your blood pressure continues to rise despite treatment (malignant hypertension)
- You suffer from a liver disease that prevents your liver from working properly
- You currently have or have had an obstruction or narrowing in your intestines
- You have ever had an obstruction in the gullet (the *oesophagus* - the tube connecting the throat to the stomach)
- You have a Kock pouch (ileostomy after proctocolectomy)
- You suffer from inflammation of the bowel or intestines, such as Crohn's disease

Warnings and precautions

Talk to your doctor before taking Valni:

- If you suffer from low blood pressure. 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 taking other medicine to treat high blood pressure, such as beta-blockers (See “Other medicines and Valni” section)
- If you experience chest pains when you **first (within 1-4 hours)** start taking Valni, contact your doctor **immediately**
- If you are given magnesium sulphate injections and you are pregnant [may cause a severe fall in blood pressure] (See “Other medicines and Valni” section)
- If you are diabetic. The treatment for your diabetes may need to be adjusted
- If you are on kidney dialysis and you have very high blood pressure or have problems with your circulation. A significant decrease in blood pressure could occur
- If you are taking the following medicines as your blood pressure should be monitored and a reduction of Valni may need to be considered: (See “Other medicines and Valni” section)
 - Erythromycin, quinupristin,dalfopristin (used to treat bacterial infections)
 - Ritonavir (used to treat HIV)
 - Ketoconazole (used to treat fungal infections)
 - Fluoxetine and Nefazodone (used to treat depression)
 - Valproic acid (used to treat convulsions and epilepsy)
 - Cimetidine (used to treat stomach ulcers)
- If you are pregnant or breast feeding. (See “Pregnancy and breast-feeding” section)

Other medicines and Valni

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

Valni **must not be taken** with the following:

- Rifampicin, used to treat bacterial infections

Medicines which **may interact** with or be affected by Valni:

- Medicines used to as a muscle relaxant during surgery e.g. tubocurarine (anaesthetic). If you are due to have an operation, you should make sure that your anaesthetist knows you are taking Valni
- Medicines used to treat bacterial infections e.g. erythromycin, azithromycin (macrolide antibiotics) and quinupristin/dalfopristin (combination antibiotic)
- Medicines used to treat HIV e.g. ritonavir (protease inhibitors)
- Medicines used to treat fungal infections e.g. ketoconazole
- Medicines used to treat depression e.g. fluoxetine and nefazodone
- Medicines used to treat convulsions and epilepsy e.g. phenytoin, valproic acid and carbamazepine
- Medicines used to treat and prevent the recurrence of ulcers e.g. Cimetidine
- Medicines used to treat heart burn e.g. cisapride
- Medicines used to treat insomnia or anxiety e.g. phenobarbital
- Medicines used to treat high blood pressure e.g. atenolol (beta-blockers), diltiazem (calcium channel blocker), lisinopril (ACE inhibitors), indapamide (diuretics), tadalafil (PDE5 inhibitors), methyl dopa (alpha-adrenergic agonists), losartan (angiotensin receptor antagonists)
- Medicines used to treat an irregularity in the heartbeat e.g. quinidine (arrhythmias)
- Medicines used to prevent the rejection of transplanted organs e.g. tacrolimus(immunosuppressants)
- Medicines used to treat heart problems such as heart failure e.g. digoxin
- Medicines used to treat asthma, bronchitis, emphysema and other lung and airway related problems e.g. theophylline (xanthine-derivative bronchodilators)
- If you are given magnesium sulphate injections and you are pregnant (may cause a severe fall in blood pressure)
- Urine tests: Valni may interfere with the results of certain urine tests

Valni with food and drink

Do not drink grapefruit juice or eat grapefruit whilst being treated with this medicine. Grapefruit juice can increase the amount of Nifedipine (the active ingredient in Valni) in the blood. This effect can last at least 3 days after having grapefruit juice.

Valni and alcohol

During treatment with Valni, it is advisable not to drink alcohol as this may cause you to feel sick, dizzy, extremely tired or suffer headaches (see “Driving and using machines section”).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

If you are pregnant you should not take Valni. Valni should only be taken by pregnant women suffering from severely high blood pressure where standard treatment has failed.

Breast-feeding

If you are breast-feeding, you must not take Valni. You should stop breast-feeding before taking this medicine. Nifedipine (the active ingredient in Valni) has been reported to be excreted in human milk and the effects are not known

Fertility

In vitro fertilisation:

If you are a man and have been repeatedly unable to father a child by in vitro fertilisation (IVF), and no other explanation has been found, it is possible that your sperm function may be affected by medicines such as Valni.

Driving and using machines

Valni may make you feel sick, dizzy, extremely tired or suffer headaches. If any of these symptoms are experienced, do not drive or operate machinery or pursue any activity in which full attention is required.

These symptoms are more likely to occur when you first start treatment, change tablets or if you have drunk alcohol (see “Valni and alcohol” section).

Valni contains lactose

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 Valni

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

- These tablets should be swallowed whole (**not broken, chewed or crushed**) with sufficient fluid (e.g. water)
- **Do not** drink grapefruit juice or eat grapefruit whilst being treated with this medicine (see “Valni with food and drink” section)

The recommended dose is:

Adults

The recommended starting dose is one tablet (20mg) every 12 hours. Your doctor may increase the dose to two tablets (40mg) every 12 hours.

Patients with liver problems

If you suffer from any liver problems, your doctor may need to adjust the dose and should monitor you carefully whilst you are being treated with Valni.

Elderly patients:

The dose may need to be adjusted (lowered)

Use in children

Valni is **not** recommended for use in children and adolescents below 18 years of age, because the safety and efficacy of Nifedipine (the active ingredient in Valni) has not been established.

If you have taken more Valni than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

The symptoms of overdose include: very low blood pressure, fast/slow heart beat, increased blood sugar level, increased acidity in the blood, high/low levels of potassium in the blood, heart problems, drowsiness, dizziness, confusion, feeling or being sick, lack of energy (lethargy), flushing, low blood oxygen levels, a lack of consciousness to point of coma and excess collection of watery fluid in the lungs.

If you forget to take Valni

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose **do not** take a double dose to make up for a forgotten dose.

If you stop taking Valni

Treatment with Valni should not be suddenly stopped.

It is important that you keep on taking Valni for as long as your doctor has told you to. **Do not** stop taking the tablets even though you may feel better. **Do not stop** or change your treatment before talking to your doctor.

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.

Stop taking Valni and seek medical advice immediately if you develop the following symptoms:

- Chest pain or worsening of existing chest pain (angina pectoris) within 1 - 4 hours of taking your first dose of this medicine
- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Severe blistering of the skin, mouth, eyes and genitals (Toxic Epidermal Necrolysis) [TEN]

Common side effects (may affect up to 1 in 10 people)

- Headache
- Swelling of parts of the body, particularly the ankles (oedema)
- Constipation
- Widening of blood vessels (vasodilatation). (A distinct fall in blood pressure can occur in dialysis patients with malignant hypertension [very high blood pressure that comes on suddenly and quickly] and hypovolaemia [severe blood and fluid loss making the heart unable to pump enough blood to the body] as a result of vasodilation)
- Reddening of the face (flushing)
- Feeling unwell

Uncommon side effects (may affect up to 1 in 100 people)

- Anxiety
- Sleep disorders
- Feeling of dizziness or "spinning" (vertigo)
- Severe headache (migraine)
- Shaking (tremors)
- Sight disturbances
- Faster heartbeat (tachycardia)
- Feeling your heartbeat (palpitations)
- Low blood pressure (hypotension)
- Fainting (syncope)

- Blocked nose
- Nose bleed
- Stomach and abdominal pain
- Indigestion
- Feeling bloated/wind (flatulence)
- Dry mouth
- Feeling sick (nausea)
- Temporary increase in liver enzymes (detected through blood test)
- Flushing of the skin
- Muscle cramps
- Swelling of the joints
- Increased production of urine (polyuria)
- Painful or difficult urination (dysuria)
- Difficulty achieving or maintaining an erection
- Unspecific pain
- Chills

Rare side effects (may affect up to 1 in 1,000 people)

- Tingling or numbness in the hands or feet (paraesthesia) or abnormal sense of touch (dysaesthesia)
- Lack of energy (lethargy)
- Swelling of the gums (gingivitis/gingival hyperplasia) [reversible following withdrawal of this medicine]
- Itching (pruritus)
- Skin rashes with the formation of wheals (urticaria)
- Rashes
- Increased need to pass urine

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

- More prone to infections. This may be due to a severe reduction in number of white blood cells (agranulocytosis, leucopenia)
- Increase in blood sugar levels (hyperglycaemia)
- Decreased skin sensitivity to pain or touch (hypoesthesia)
- Feeling sleepy or drowsy (somnia)
- Eye pain
- Chest pain (angina)
- Breathlessness
- A solid mass of indigestible material that collects in your digestive tract, sometimes causing a blockage (bezoar)
- Difficulty swallowing (dysphagia)
- Abdominal pain caused by obstruction of the gut or ulcers in the gut
- Heartburn caused by stomach acid coming up from the stomach into the gullet (gastroesophageal sphincter insufficiency)
- Being sick (vomiting)
- Yellowing of the skin or whites of the eyes (jaundice)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Skin rash caused by small blood vessels bleeding into the skin (palpable purpura)
- Muscle pain (myalgia), joint pain (arthralgia)
- Excessive development of the male breast in older men (gynecomastia) [reversible following withdrawal of this medicine]
- Build up of bile acids in the bloodstream causing persistent itch (cholestasis) [reversible following withdrawal of this medicine]

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 internet at

(www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Valni

- Keep out of the sight and reach of children.
- Store below 25°C. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton/blister after "EXP". The expiry date refers to the last day of that month.
- 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 to protect the environment.
- If you should notice any defects with these tablets such as discolouration and chipping you must take them to your pharmacist for advice before taking them.

6 Contents of the pack and other information

What Valni contains:

Each modified released tablet contains 20mg of Nifedipine.

The other ingredients are: microcrystalline cellulose, lactose, corn starch, talc, hydroxypropylmethyl cellulose, magnesium stearate, polysorbate 80, polyethylene glycol 4000, iron oxide (E172) and titanium dioxide (E171).

What Valni looks like and contents of the pack:

Valni Tablets are pale red, round, biconvex tablets with the marking NIF20 on one side.

Valni is available in:

Valni Tablets are available in packs of 28, 30, 56, 60, 84, 100, 250, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Ltd.
220 Butterfield,
Great Marlings,
Luton
LU2 8DL
United Kingdom

Product Licence Number:

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