

Package leaflet: Information for the user

Verap 120mg & 240mg Prolonged Release Tablets

Verapamil Hydrochloride

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

1 What Verap is and what it is used for

Verap belongs to a group of medicines called calcium antagonists. The active substance in Verap is verapamil hydrochloride.

Verap is used to:

- treat mild to moderate high blood pressure
- prevent a certain type of chest pain called angina pectoris

If you suffer from high blood pressure Verap works by relaxing blood vessels, so that blood passes through them more easily.

If you suffer from angina Verap works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Verapamil does not provide immediate relief of chest pain from angina.

2 What you need to know before you take Verap

Do not take Verap if you have any of the following conditions:

- allergic to verapamil or to any of the other ingredients of this medicine (listed in section 6).
- insufficient blood supply to your tissues, e.g. caused by severe heart troubles (cardiovascular shock)
- very low blood pressure
- acute heart attack complicated by slow heartbeat

- second or third degree heart block or an electrical abnormality of the heart (atrial fibrillation/flutter) causing periods of very fast heartbeat (Wolff-Parkinson-White syndrome)
- heart failure
- sick sinus syndrome (irregular heartbeat)
- had a heart attack in the last 7 days
- you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Verap:

- if you have suffered from heart failure or 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- if you have a fast heartbeat
- if you suffer from progressive weakness and degeneration of muscles
- if you have a slow heart rate of less than 50 beats/min
- if your systolic blood pressure is less than 90mmHg
- if you have reduced liver function
- if you have a condition where the nerve to muscle transmission is affected e.g. myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy
- if you have reduced kidney function.

Other medicines and Verap

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

Verap and other medicines interact with each other.

It is therefore important to tell your doctor if you take any of the following medicines:

- **Medicines to treat high blood pressure**, e.g. beta-blockers (propranolol, metoprolol), alpha-blockers (prazosin, terazosin)
- **Other medicines for high blood pressure or an abnormal heartbeat** e.g. digitoxin, digoxin, disopyramide, flecainide and quinidine
- **Theophylline** (used to treat asthma)
- **Carbamazepine, phenobarbital** (anti-epileptic)
- **Glyburide** (used to treat diabetes)
- **Medicines used to treat gout** e.g. colchicine and sulfinpyrazone
- **Clarithromycin, erythromycin, telithromycin, rifampicin** (antibiotic)
- **Doxorubicin** (an anti-cancer medicine)
- **Medicines to treat depression** including St John's Wort (*Hypericum perforatum*; a herbal medicine), imipramine and lithium
- **Medicines to treat anxiety** e.g. buspirone and midazolam (also used as a sedative or anaesthetic)
- **Cimetidine** (stomach ulcer medicine)
- **Medicines to prevent organ transplant rejection known as immunosuppressants** such as ciclosporin, everolimus, sirolimus, tacrolimus.
- **Medicines to lower cholesterol levels** e.g. atorvastatin, lovastatin, simvastatin
- **Almotriptan** (used to treat migraine)
- **Aspirin** (used to relieve pain and reduce fever)
- **Ritonavir** (antiviral medicine)

- **Muscle relaxants and neuromuscular blockers** as used in anaesthetics
- **Ivabradine** (for the treatment of certain heart diseases) - see section 2
- **Dabigatran** (medicine to prevent the formation of blood clots)
- Medicines known as “direct oral anticoagulants” such as dabigatran, apixaban, rivaroxaban and edoxaban.

Tell your surgeon or dentist that you are taking Verap if surgery is planned as it may affect the anaesthetic used.

Verap with food, drink and alcohol

You can take Verap independently of food. You should not take this medicine with grapefruit juice. Verap will increase the time your body takes to get rid of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take Verap unless specifically prescribed by your doctor. If you are breast-feeding, do not take Verap.

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

Driving and using machines

Be careful if you drive or operate machinery if you take this medicine. Verap may not directly affect your ability to drive or operate machinery. However, side effects such as dizziness may interfere with this ability, particularly together with alcohol.

Verap contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains lactose.

Verap 120mg Prolonged Release Tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Verap 240mg Prolonged Release Tablets contain 29.4 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.47% of the recommended maximum daily dietary intake of sodium for an adult.

3 How to take Verap

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

Dosage

High blood pressure

Adults

The recommended dose is 240 mg in the morning increasing if necessary after one week to 240 mg in the morning and 240 mg in the evening with an interval of 12 hours between the tablets.

Elderly patients

The recommended dose is 120 mg in the morning. Your doctor may choose to increase the dose if necessary.

Angina pectoris

Adults

The usual dose is 120 – 240 mg twice daily. A low starting dose is recommended for new patients increasing the dose if necessary.

Children and adolescents:

There are no data on the use of verapamil prolonged release tablets in children and adolescents.

Patients with reduced liver function

Follow your doctor's instructions.

Method of administration

Swallow the tablets whole with a glass of water; you can take them with or without food. You should not take this medicine with grapefruit juice.

Do not chew or crush the tablets.

This medicine is for oral use only.

If you take more Verap than you should

Contact your doctor, an emergency department or a pharmacy immediately if you have taken more Verap than recommended in the information leaflet or more than your doctor has prescribed. An overdose can cause low blood pressure, shock, loss of consciousness, heart conduction disorders that affect heart rhythm or a life threatening heart condition known as asystole. It may need to be treated in hospital.

If you forget to take Verap

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember and then take the next dose at the right time.

If you stop taking Verap

Do not stop taking Verap without talking to your doctor.

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

4 Possible side effects

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

Tell your doctor immediately if you experience any of the following side effects:

- Yellowing of the skin or eyes, a fever or tenderness around the tummy.
These are signs that your liver may not be functioning as well as usual
- Palpitations, chest pains for the first time or chest pains becoming more frequent, swollen ankles, hot and painful hands or feet

- Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue or severe skin rash. These may be symptoms of an allergic reaction.

Common: may affect up to 1 in 10 people

- dizziness
- headache
- slow heartbeat
- flushing
- low blood pressure
- constipation
- nausea (feeling sick)
- swollen feet or ankles

Uncommon: may affect up to 1 in 100 people

- irregular or fast heartbeat
- stomach pain
- tiredness

Rare: may affect up to 1 in 1000 people

- a tingling or prickling feeling on the skin
- tremor
- drowsiness
- a ringing sound in the ears (tinnitus)
- being sick
- sweating a lot more than usual

Not known: frequency cannot be estimated from the available data

- allergic reactions
- increased blood sugar levels
- high potassium levels
- movement disorders
- paralysis
- seizures
- nervousness
- reduced sense of touch and nerve damage
- vertigo
- heart attack
- heart failure
- unusual heartbeat
- burning pain, redness and swelling of the hands, feet or other extremities
- difficulty in breathing
- stomach discomfort
- swollen gums which start to spread over the teeth
- bowel obstruction
- liver problems
- swelling of the mouth, lips or tongue or severe skin rash
- rash
- sensitivity to light

- hair loss (alopecia)
- itching
- aches and pains in the joints and/or muscles and muscle weakness
- kidney problems
- impotence
- breasts that leak milk
- breast enlargement or swelling
- greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to produce milk
- increase in liver enzymes
- problems with an artificial pacemaker

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 HPRA Pharmacovigilance.

Website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Verap

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.

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 Verap contains:

- The active substance is verapamil hydrochloride.

Each Verap 120mg Prolonged Release Tablet contains 120 mg of verapamil hydrochloride.

Each Verap 240mg Prolonged Release Tablet contains 240 mg of verapamil hydrochloride.

- The other ingredients of Verap 120mg Prolonged Release Tablets are sodium alginate, povidone, microcrystalline cellulose, colloidal silica anhydrous, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000 and ferric oxide yellow (E172).

The other ingredients of Verap 240mg Prolonged Release Tablets are sodium alginate, povidone, microcrystalline cellulose, colloidal silica anhydrous, magnesium stearate, quinolone yellow E104, indigotine E132, lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000.

What Verap looks like and the contents of the pack

Verap 120mg Prolonged Release Tablets are beige, round, biconvex, film-coated, prolonged release tablets with a score notch.

Verap 240mg Prolonged Release Tablets are green oblong, biconvex, film-coated, prolonged release tablets with a score notch on both sides.

The score line should not be used to break the tablets.

Your tablet comes in

- Blister packs of 30 and 100 tablets and sample packs of 10

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH., Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

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