

Verapamil 40 mg, 80 mg and 120 mg Tablets verapamil hydrochloride

Package leaflet: Information for the user

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

1 What Verapamil is and what it is used for

Verapamil is a calcium channel blocker, which expands your blood vessels to allow more blood to flow through them. It also acts on the nerve signals passing through the heart muscle, which can help to correct certain types of abnormal heart rhythm.

Verapamil is used:

- to prevent or treat angina (chest pain) and certain abnormal heart rhythms
- to treat high blood pressure.

2 What you need to know before you take Verapamil

Do not take Verapamil

- if you are allergic to Verapamil or any of the other ingredients of this medicine (listed in section 6).
- if you have a very slow heart-beat of less than 50 beats per minute.
- if you suffer from heart problems including sick sinus syndrome (causing a slow heart rate).

- if you suffer Lown-Ganong-Levine or Wolff-Parkinson-White syndrome (causing palpitations).
- if you have had a heart attack which has been followed by a slow heart rate, low blood pressure or breathlessness.
- if you have very low blood pressure due to heart problems.
- if you have a **weak heart** (causing breathlessness and tiredness).
- if you have problems of conduction in the heart such as sino atrial block and 2nd or 3rd degree atrioventricular block.
- if you suffer from porphyria (a rare inherited disease affecting the blood).
- if you have been given a muscle relaxant called dantrolene by injection.
- if you have been given a type of medicine called a Beta-blocker by injection.
- if you drink grapefruit juice.
- if you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

This medicine is not suitable for anyone under the age of 18 years old.

Talk to your doctor before taking this product if any of the above apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Verapamil

- if you have liver problems.
- if you have a heart condition.
- if you are pregnant or breast-feeding.
- if you have any kidney problems.
- if you have low blood pressure.
- if you have myasthenia gravis, Lambert-Eaton syndrome or Duchenne muscular dystrophy (nervous conditions which cause muscle weakness).
- if you are taking medicine for high blood cholesterol (a "statin", such as simvastatin or atorvastatin).

Children and adolescents

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

Other precautions you should take

- If you are to have an operation requiring an anaesthetic (including treatment at the dentist), tell the doctor, surgeon or dentist that you are taking Verapamil tablets.

Other medicines and Verapamil

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

- Verapamil may decrease the glucose-lowering effect of metformin.
- It is important that you talk to your doctor if you are taking or have recently taken **beta blockers**, such as propranolol, or **other drugs which lower blood pressure**, as this may result in very low blood pressure or heart failure.

You should also talk to your doctor if you are taking or have recently taken any of the following:

- Alpha blockers e.g. prazosin and terazosin used to treat high blood pressure and heart conditions.
- Diuretics (also called "water tablets").
- medicines known as "statins" such as atorvastatin, lovastatin, simvastatin used to lower cholesterol levels.
- any other medicine for high blood pressure or an abnormal heart beat (arrhythmia) such as quinidine, disopyramide, flecainide, digoxin and digitoxin.
- medicines used to treat depression (including the herbal product, St John's Wort), anxiety or psychosis e.g. imipramine, buspirone and lithium.
- medicines known as immunosuppressants such as ciclosporin, sirolimus, everolimus and tacrolimus. These are used to prevent organ transplant rejection.
- glibenclamide, used to treat certain types of diabetes.
- aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever.
- almotriptan, used to treat migraine.
- midazolam, used as a sedative or anaesthetic.
- theophylline, used to treat asthma.
- doxorubicin, an anti-cancer medicine.
- cimetidine, used to treat indigestion or stomach ulcers.
- dabigatran, an anticoagulant medicine that helps prevent blood clots.
- carbamazepine, phenytoin or phenobarbital, (phenobarbitone). These medicines are used as anti-convulsants.
- rifampicin, used to treat tuberculosis and other types of infection.

- ritonavir, used to treat HIV.
- erythromycin and telithromycin, used to treat certain types of infection.
- colchicine or sulfinpyrazone, used to treat gout.
- dantrolene, used in multiple sclerosis to relax muscles.

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

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

Verapamil with food, drink and alcohol

Do not drink excessive amounts of alcohol whilst you are taking Verapamil, as the effects of alcohol may be exaggerated. Verapamil slows the elimination of alcohol from the body. Do not drink grapefruit juice whilst you are being treated with Verapamil.

Pregnancy, breast-feeding and fertility

Verapamil is not recommended if you are pregnant, planning to become pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Verapamil may enhance and prolong the effects of alcohol. The ability to drive or operate machinery or work under hazardous conditions may be impaired. This is particularly true in the initial stages of treatment, when the dose is increased or when changing from one drug to another. If affected do not drive or operate machinery.

Verapamil contains Lactose

Patients who are intolerant to lactose should note that Verapamil tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Verapamil contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Verapamil

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 tablets should be swallowed preferably with a glass of water.

The recommended dose is:

Angina

- Adults:

Between 80 mg and 120 mg, taken three times daily.

Abnormal Heart Rhythms

- Adults:

Between 40 mg and 120 mg, taken three times daily.

- Children:

For children of up to two years, the usual dosage is half a 40 mg tablet, taken two to three times daily.

For children 2 years and above the usual dose is one to three 40 mg tablets taken two to three times a day according to age and effectiveness.

High Blood Pressure

- Adults:

Between 120 mg and 160 mg, taken twice daily. Your doctor may increase this up to a maximum of 480 mg per day.

- Children:

Your doctor will calculate the appropriate dose of Verapamil for your child based on your child's body weight and severity of the disease.

The Elderly

In the case of elderly patients, your doctor may prescribe a reduced dosage if you suffer from liver problems or kidney problems or certain heart conditions.

If you take more Verapamil than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause low blood pressure, shock, heart problems, cardiac arrest or slow heart beat. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Verapamil

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Verapamil

Do not stop taking your medicine without talking to your doctor first even if you feel better.

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

4 Possible side effects

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

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to unexpected wheezing, severe difficulty in breathing, skin rash or hives).
- Stevens-Johnson syndrome, a serious illness with blistering of the skin, mouth, eyes and genitals.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

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 middle. 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.
- Swelling of the limbs.

The following side effects have been reported at the approximate frequencies shown:

Common (affecting fewer than one person in 10 but more than one person in 100):

- abdominal pain/discomfort
- numbness
- tremor
- movement disorders
- muscle weakness
- joint or muscle pain
- tinnitus (ringing or buzzing in the ears)
- tickling or prickling feeling on the skin
- redness or burning sensation in the hands or feet
- there may be changes to some blood test results.

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

- mild constipation
- flushing.

Rare (affecting fewer than one person in 1,000 but more than one person in 10,000):

- headaches
- nausea (feeling sick), vomiting (being sick)
- soreness of the gums
- ankle swelling
- fatigue, dizziness
- impotence (inability to get or maintain an erection)
- increased concentrations of the hormone prolactin in the blood.

Very rare (affecting fewer than one person in 10,000):

- problems with your liver, but any such effects are reversible
- hair loss
- skin reactions.

The below side effects may occur if Verapamil is taken for a long time but resolve when you stop taking the tablets. Tell your doctor if:

- you develop swollen gums which start to spread over your teeth (gingival hyperplasia)
- the development of the breasts in men (gynaecomastia) which is reversible
- production of milk in men or women who are not breast-feeding (galactorrhoea).

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 Verapamil

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

Keep the tablets in the pack and do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and blister pack. 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 no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Verapamil tablets contains

- The active substance is verapamil hydrochloride. The tablets contain either 40, 80 or 120 mg of the active substance.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose (E460), sodium starch glycolate (Type A) (E576), povidone (E1201), silica anhydrous colloidal, magnesium stearate (E572), hypromellose (E464), polyethylene glycol 400 and 4000 and the colourings quinolone yellow (E104), titanium dioxide (E171), iron oxide (E172), carnauba wax and water, purified.

What Verapamil tablets look like and contents of the pack

Verapamil 40 mg are biconvex, film-coated tablets engraved 1T1 or 40/0234 and plain on the reverse.

Verapamil 80 mg are biconvex, film-coated tablets engraved 2T1 or 80/0235 and plain on the reverse.

Verapamil 120 mg are biconvex, film coated tablets engraved 3T1 or 120/0241 and plain on the reverse.

Verapamil is packed in Polypropylene or HDPE containers with polyethylene or LDPE lids or child resistant caps in packs of 100 and 250 tablets. Also in PVdC coated PVC film with hard temper aluminium foil blister strips in packs of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Teva Pharmaceutical Works Private Limited Company, Pallagi Street 13, Debrecen, H-4042, Hungary

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