

Patient Information Leaflet

Verapamil 40mg/5ml Oral Solution

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

The name of your medicine is Verapamil 40mg/5ml Oral Solution (called Verapamil in this leaflet). It contains verapamil hydrochloride. This belongs to a group of medicines called calcium channel blockers. The heart muscle and the muscle in your blood vessel walls need calcium to contract and tighten.

Verapamil stops calcium from getting into these muscles. This:

- relaxes your heart and blood vessels
- makes your heart pump out less blood every time it beats
- slows down your heart rate (pulse).

Verapamil can be used to:

- treat high blood pressure (hypertension)
- treat chest pain (angina)
- treat heart rhythm problems such as heart flutter (supraventricular tachycardia).

2. What you need to know before you take Verapamil

Do not take Verapamil and tell your doctor if:

- you are allergic (hypersensitive) to verapamil or any other ingredients in this liquid (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have a problem where your heart beats at the wrong time, too fast or too slow such as:
 - second- or third-degree atrioventricular block or sick sinus syndrome (unless you have a pacemaker)
 - sino-atrial block
 - Wolff-Parkinson-White syndrome or Lown-Ganong-Levine syndrome
 - severe bradycardia
- you are already taking a medicine containing ivabradine for the treatment of certain heart diseases

- you have an inherited blood disorder known as porphyria
- you have low blood pressure (hypotension)
- you have been given intravenous dantrolene.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

You will not be given Verapamil if:

- you have a sudden and rapid fall in blood pressure (cardiogenic shock)
- you have heart failure that is not being treated
- you have a sudden heart attack, particularly if a slow heart beat, low blood pressure or a type of heart failure called ‘left ventricular failure’.

You will not be given this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take special care with Verapamil

Before you take Verapamil, tell your doctor if:

- you have liver or kidney problems
- you have an abnormally slow heart beat (bradycardia)
- you have first degree atrioventricular block. This is a disorder where parts of your heart may beat at the wrong time causing it not to pump blood around the body very well
- you have a nerve to muscle transmission disease, such as myasthenia gravis, Lambert-Eaton syndrome or advanced Duchenne muscular dystrophy
- you are pregnant or breast feeding. See ‘Pregnancy and Breast-feeding’ section below.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Verapamil.

Having tests and operations while you are taking Verapamil

- your doctor will monitor your blood pressure regularly
- if you are having an anaesthetic, tell your doctor or dentist that you are taking this medicine.

Other medicines and Verapamil

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Verapamil can affect the way some other medicines work. Also, some medicines can affect the way Verapamil works.

Verapamil may decrease the glucose-lowering effect of metformin.

You must not be given intravenous dantrolene (a medicine to relax muscles) at the same time as verapamil. If you go to hospital, tell them you are taking verapamil.

In particular, tell your doctor if you are taking any of the following:

- digoxin, digitoxin or ivabradine, used for heart failure
- flecainide or quinidine, used to treat arrhythmias
- medicines used to lower blood pressure and treat abnormal heart rhythms, including quinidine, flecainide, alpha-blockers (e.g. prazosin and terazosin) and beta-blockers (e.g. propranolol and metoprolol). If you are going to be given a beta-blocker by injection, tell the doctor that you are taking Verapamil
- simvastatin, atorvastatin or lovastatin, used to lower cholesterol levels
- diuretics (water tablets)
- dabigatran, used to prevent blood clots
- medicines used to treat depression, anxiety or psychosis. These may include imipramine, buspirone, lithium or the herbal product St John’s Wort
- medicines used to treat epilepsy such as carbamazepine, phenytoin or phenobarbital
- glibenclamide, used to treat certain types of diabetes

- midazolam, used to make you sleepy
- theophylline, used for asthma
- doxorubicin, used to treat cancer
- almotriptan, used to treat migraine
- aspirin, used to relieve pain and reduce fever
- cimetidine, used to treat stomach ulcers
- rifampicin, used to treat TB (tuberculosis)
- medicines used to treat infections such as ketoconazole, erythromycin, clarithromycin and telithromycin
- ritonavir, used to treat HIV
- medicines that are given after organ transplants to stop the body rejecting the organ such as ciclosporin, everolimus, sirolimus and tacrolimus
- colchicine or sulfapyrazone, used in the treatment of gout.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Verapamil.

Verapamil with food, drink and alcohol

- do not drink grapefruit juice whilst you are taking Verapamil. This is because grapefruit juice may change the blood levels of your medicine.
- you should monitor the amount of alcohol you drink whilst taking Verapamil (see driving and using machines below).

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

- you must only take this medicine in the first 3 months of pregnancy (1st trimester) if your doctor thinks it is essential.
- you must only take this medicine when you are breast-feeding if your doctor thinks it is necessary.

Driving and using machines

When starting a new medicine, you may find that your ability to drive a car or use machinery can be impaired. You should take care when driving, using machines or working under hazardous conditions until you know how you react to this medicine.

This medicine can affect the way the body gets rid of alcohol. This means that you may not have to drink as much for your blood alcohol levels to be above the legal limit to drive. It will also take you longer to sober up.

Verapamil contains liquid maltitol, propylene glycol, ethanol and benzoic acid:

- liquid maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- propylene glycol (E1520). This medicine contains 500mg propylene glycol in each 5ml dose. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you are pregnant, breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- ethanol. This medicine contains 2.1mg of alcohol (ethanol) in each 5ml, which is equivalent to less than 1ml beer or 1ml wine. The small amounts of alcohol in this medicine will not have any noticeable effects.
- benzoic acid (E210). This medicine contains 5mg benzoic acid in each 5ml dose.
- this medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium free'.

3. How to take Verapamil

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 40mg of verapamil hydrochloride in each 5ml.
- take this medicine by mouth.

Adults

The usual dose is:

For high blood pressure

- take 120mg twice a day.
- your doctor may increase this to a maximum of 160mg twice a day.

For angina

- take 120mg three times a day.
- your doctor may lower this dose.

Heart Rhythm Disorders

- take 40mg to 120mg three times a day.

Children

The usual dose for children is:

- up to 2 years of age: 20mg two or three times a day.
- 2 years of age and above: 40mg to 120mg three times a day.
- children under 3 months should not be given this medicine.

Older people

The dose will be the same as that for adults. If you have a kidney or liver problem, your doctor may lower your dose.

If you take more Verapamil than you should

If you take more Verapamil than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Verapamil

- if you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Verapamil

Do not stop taking this medicine without talking to your doctor first. If you stop taking this medicine it may make your condition worse.

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

4. Possible side effects

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

If you have any of the following, stop taking Verapamil and see a doctor straight away. You may need urgent medical attention:

- If you have an allergic reaction to Verapamil.
The signs of an allergic reaction may include:
 - any kind of skin rash, flaking skin, boils or sore lips and mouth
 - sudden wheezing, fluttering or tightness of your chest or collapse
 - swelling of your face, lips, tongue or throat or difficulty breathing or swallowing
 - bruise like, red / purple patches on the skin and hair loss
- heart problems such as slow or fast heart beats, unusual heart beats, heart attack and heart failure.
This is more likely if you are taking high doses or you already have damage to your heart.

If you get any of the following side effects, see your doctor as soon as possible:

- swelling of your ankles
- swelling of your blood vessels which may show as pain in the fingers and toes and numbness
- stomach pain / discomfort
- muscle or joint pain
- shaking
- unusual body movements, particularly of your face, neck, eyes and jaw.

Tell your doctor if you get any of these side effects:

- breast development in older men or difficulty in getting an erection
- constipation
- flushing of your face
- ringing in the ears
- headaches, feeling dizzy or tired
- feeling sick (nausea) or being sick (vomiting)
- swollen and overgrown gums
- muscle weakness.

This medicine may also cause side effects in your liver and breasts that will only be detected through tests performed by your doctor.

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 out of the sight and reach of children.
- Do not store above 25°C.
- Any unused medicine should be disposed of 3 months after you have opened it.
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year).
- The expiry date refers to the last day of that month.
- Do not use Verapamil if you notice a change in the appearance or smell of the medicine. Talk 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 to protect the environment.

6. Contents of the pack and other information

What Verapamil contains

- The active ingredient is verapamil hydrochloride. Each 5ml of solution contains 40mg of verapamil hydrochloride.
- The other ingredients are propylene glycol (E1520), benzoic acid (E210), liquid maltitol (E965), dill water concentrate (contains ethanol), liquorice flavour, citric acid monohydrate (E330), sodium citrate (E331) and purified water.

What Verapamil looks like and contents of the pack

A clear to slightly cloudy colourless liquid.

It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder:

Essential Pharma Ltd, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.

Manufacturer:

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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