

PACKAGE LEAFLET: INFORMATION FOR THE USER

Veramil 40 mg Film-coated Tablets Veramil 80 mg Film-coated Tablets Veramil 120 mg Film-coated 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 Veramil Tablets are and what they are used for
2. What you need to know before you take Veramil Tablets
3. How to take Veramil Tablets
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1. What Veramil Tablets are and what they are used for

Veramil Tablets contain the active substance Verapamil hydrochloride. Veramil belongs to a group of medicines called calcium channel blockers. It works by blocking the movement of calcium into the cells of the heart and blood vessels. As a result, Veramil relaxes blood vessels which leads to lowering of high blood pressure. This increases the supply of blood and oxygen to the heart while also relaxing the heart muscle.

Veramil is used to:

- Treat high blood pressure (hypertension)
- Manage and prevent angina
- Treat and prevent certain types of abnormal heart rhythm (supraventricular tachycardia).

2. What you need to know before you take Veramil Tablets

Do not take Veramil Tablets if you:

- are allergic to verapamil hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have heart failure or severe problems with the impulse and rhythm of the heart (second or third degree atrioventricular block)
- you have problems with your heart valves or sick sinus syndrome (irregular heartbeat)
- you are being treated with injectable beta blockers
- have recently suffered a heart attack
- suffer from a slow heart rate (bradycardia)
- have severely low blood pressure as a result of heart problems (hypotension)
- have Wolff-Parkinson-White syndrome (rapid heart rate sometimes with dizziness or faintness or which causes palpitations)
- are pregnant, planning to become pregnant or are breast-feeding (see Pregnancy and breast-feeding).

Veramil Tablets should not be taken with grapefruit juice as this may affect how your medicine works.

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

Warnings and precautions

Talk to your doctor before using Veramil Tablets if any of the following apply to you:

- if you suffer from any heart condition and are taking other medicines for this, especially if you feel your condition is becoming worse
- if you have low blood pressure
- if you are an elderly patient
- if you are planning a family
- if you have any liver or kidney problems
- if you are taking another medicine called colchicine
- if you suffer from any neuromuscular diseases or conditions which cause muscle weakness such as myasthenia gravis, Lambert-Eaton syndrome or advanced Duchenne muscular dystrophy
- if you suffer from cardiomyopathy (a disease of the heart muscle)
- if you have ever suffered from heart failure, or first degree AV block or an irregular heart beat
- if you have been told that you have an intolerance to certain kinds of sugar such as lactose and sucrose
- if you are going to have surgery as some of the medicines used as part of a general anaesthetic may interfere with the way Veramil Tablets work.

Children and adolescents

Do not give this medicine to children and adolescents because it is unlikely to be safe.

Other medicines and Veramil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular tell your doctor if you are taking any of the following:

- medicines to treat high blood pressure, such as propranolol, prazosin, terazosin or metoprolol
- medicines to treat irregular heart rates, such as quinidine, flecainide
- medicines to treat other heart conditions, such as digoxin, digitoxin
- medicines to treat high cholesterol, such as simvastatin, atorvastatin or lovastatin
- medicines to treat epilepsy, such as carbamazepine, phenobarbital
- medicines to treat depression or anxiety, such as imipramine, midazolam
- medicines to treat fungal infections, such as fluconazole or itraconazole
- antibiotics, such as erythromycin, rifampicin, clarithromycin or telithromycin
- medicines to treat cancer, such as doxorubicin
- medicines used to suppress the body's immune system, such as tacrolimus, cyclosporine, everolimus or sirolimus
- HIV medicines such as ritonavir or nelfinavir
- medicines used to treat panic or anxiety, such as buspirone
- medicines used to treat gout, such as sulfinpyrazone, colchicine
- St. John's Wort
- dabigatran (medicine to prevent the formation of blood clots)

In addition to the above, you should tell your doctor if you are taking any of the following medicines:

- theophylline used in the treatment of asthma
- glyburide used in the treatment of diabetes
- cimetidine used for the treatment of stomach ulcers
- almotriptan to treat migraines
- water pills (diuretics)

- lithium used in the treatment of mania and other mental illnesses
- aspirin, a non-steroidal anti-inflammatory painkiller (NSAID) used to relieve pain and reduce fever
- or if you are going to have surgery (see Warnings and precautions)

Veramil Tablets with food, drink and alcohol

Do not drink grapefruit juice whilst taking Veramil Tablets. Grapefruit juice may increase the effect of Veramil Tablets.

The effect of alcohol may be increased when taken together with Veramil Tablets. If you are concerned about how much alcohol you can drink while you are taking this medicine discuss this with your doctor.

Pregnancy and breast-feeding

The use of Veramil Tablets during pregnancy is not recommended. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Veramil Tablets should not be used whilst you are breast-feeding. If you are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Veramil Tablets may cause side effects such as dizziness, especially at the start of treatment. Therefore your ability to drive and use machines may be impaired whilst taking Veramil Tablets. This is particularly true in the initial stages of treatment, when changing over from another drug, and also with respect to the consumption of alcohol.

Veramil Tablets contain the sugars lactose and sucrose

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 Veramil Tablets

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

Do not chew or crush the tablet.

Angina: the usual dose is 120 mg three to four times a day.

High blood pressure: the usual dose is 40 to 120 mg three to four times a day.

Arrhythmias: the usual dose is 40 to 120 mg three to four times a day.

If you take more Veramil Tablets than you should

If you or someone else takes too many Veramil Tablets contact your nearest hospital emergency department or tell your doctor immediately. Show the doctor your pack of tablets.

If you forget to take Veramil Tablets

If you forget to take a tablet, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose but take your usual dose at the normal time. Do not take a double dose to make up for forgotten doses.

If you stop taking Veramil Tablets

Continue to take your medicine for as long as your doctor tells you to. If you suddenly stop taking Veramil Tablets your symptoms may get worse. Do not stop taking your medicine just because you feel better.

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.

If you experience any of the following side effects, seek immediate medical attention:

- skin reactions with blistering or ulceration of the skin, mouth, eyes and genitals (Stevens Johnson syndrome)
- yellowing of the skin or eyes, a fever or tenderness around the tummy
- serious allergic reaction which causes swelling of the face, mouth, lips, tongue or throat (angioneurotic oedema) or severe skin rash
- wheezing and difficulty breathing
- feeling faint or fainting
- a tight feeling in the chest
- swollen ankles or hot and painful hands and feet
- a rapid heart beat or heart palpitations.

These are serious side effects and require immediate medical attention.

Other Possible Side Effects:

Common: (may affect up to 1 in 10 people)

- headaches, dizziness
- slow heart beat, low blood pressure
- flushing
- constipation
- feeling sick
- swelling of the limbs

Uncommon: (may affect up to 1 in 100 people)

- fast or irregular heart beat
- pain in the stomach
- tiredness or fatigue

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

- 'pins and needles', involuntary shaking
- feeling very tired or sleeping for longer than usual
- 'ringing in the ears'
- being sick
- excessive sweating

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

- having a fit, involuntary spasm or other movement disorders
- nervousness,
- spinning sensation
- reddening of the skin including face or neck
- partial or complete blockage of the bowel
- swelling of the gums
- discomfort in the stomach
- hair loss
- skin problems such as rash, itching, discolouring, swelling like hives, tingling or prickling feeling, blisters, ulcers, numbness
- weakness

- aches or pains in the joints and/or muscles
- impotence, breast growth in men
- increase in levels of a hormone called prolactin which may occur with milk production spontaneous lactation (men and women)
- liver problems which can be detected by blood tests done by your doctor

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; or E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Veramil Tablets

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

Do not store above 25°C. Store in the original package in order to protect from light. Do not use Veramil Tablets after the expiry date which is stated on the carton and container label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration in the tablets. 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 Veramil Tablets contain

- The active substance is verapamil hydrochloride. Each Veramil 40 mg film-coated Tablet, Veramil 80 mg film-coated Tablet and Veramil 120 mg film-coated Tablet contains 40 mg, 80 mg and 120 mg of verapamil hydrochloride respectively.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, gelatin, magnesium stearate, colloidal anhydrous silica, hypromellose, sucrose, titanium dioxide (E171), polysorbate 80 and glycerol.

What Veramil Tablets look like and contents of the pack

Veramil Tablets are white, convex, film-coated tablets. Veramil 40 mg Film-coated Tablets are coded with VL 40. Veramil 80 mg Film-coated Tablets are coded with VL 80. Veramil 120 mg Film-coated Tablets are coded with VL 120. Veramil Tablets are supplied in a HDPE container of 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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