

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Vera-Til SR 120mg and 240mg 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 Vera-Til SR is and what it is used for
2. What you need to know before you take Vera-Til SR
3. How to take Vera-Til SR
4. Possible side effects
5. How to store Vera-Til SR
6. Contents of the pack and other information

1 What Vera-Til SR is and what it is used for

The active ingredient in this medicine is called verapamil hydrochloride. It belongs to a group of medicines called calcium channel blockers. It works by reducing the heart rate and increasing coronary blood flow.

Vera-Til SR is used:

- To treat high blood pressure (hypertension)
- To help control angina (chest pain)
- After a heart attack in order to prevent further heart attacks

2 What you need to know before you take Vera-Til SR

Do not take Vera-Til SR:

- If you are allergic to verapamil (the active ingredient in Vera-Til SR) or any of the other ingredients of this medicine (listed in section 6)
- If you have had a heart attack, which has been followed by a slow heart rate, low blood pressure or breathlessness
- If you have a weak heart which may cause breathlessness and tiredness
- If you have an abnormal or slow heartbeat (unless controlled by a pacemaker) or had heart block
- If you have had congestive heart failure
- If you have low blood pressure
- If you have blocked veins in your heart
- If you have Wolff-Parkinson-White syndrome (a heart condition)
- If you are taking ivabradine for heart conditions (see "Other medicines and Vera-Til SR" section)

Warnings and precautions

Talk to your doctor before taking Vera-Til SR:

- If you have liver disease
- If you have suffered heart failure or have heart problems
- If you are taking statins for lowering cholesterol, such as simvastatin, atorvastatin or lovastatin (see "Other medicines and Vera-Til SR" section)
- If you have a neuro-muscular disorder such as myasthenia gravis (chronic fatigue and muscular weakness), Lambert-Eaton syndrome or advanced Duchenne muscular dystrophy

Your blood pressure should be checked regularly when you are being treated with Vera-Til SR.

Other medicines and Vera-Til SR

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

Medicines which **may interact with or be affected by** Vera-Til SR:

- Aspirin, (Non-Steroidal Anti-Inflammatory Drug [NSAID]) used to relieve pain and inflammation
- Medicines for high blood pressure and heart conditions (antihypertensives) such as:
 - Prazosin and terazosin (alpha blockers)

- Propranolol and metoprolol (beta-blockers). Vera-Til SR must not be taken with beta-blockers given by injection
- Medicines used to increase frequency of urination (diuretics)
- Vasodilators e.g. hydralazine
- Medicines for irregular heartbeat or heart failure, such as digoxin and digitoxin (cardiac glycosides)
- Other medicines for irregular or rapid heartbeat, such as flecainide, quinidine (anti-arrhythmics)
- Medicines for epilepsy, such as carbamazepine and phenytoin (anti-convulsants)
- Medicines for depression, such as imipramine (anti-depressants) and St. John's Wort (herbal medicine)
- Glibenclamide, metformin for diabetes (antidiabetic)
- Medicines used to prevent rejection after organ transplants, such as ciclosporin, everolimus, tacrolimus or sirolimus (immunosuppressants)
- Theophylline, for bronchial asthma
- Rifampicin, an antibiotic for various infections, in particular tuberculosis
- Lithium, for depression or mania
- Cimetidine, for the treatment and prevention of ulcers and indigestion
- Ivabradine, for heart conditions
- Erythromycin, telithromycin and clarithromycin, for bacterial infections
- Doxorubicin, for cancer
- Medicines used for lowering cholesterol (known as 'statins'), such as simvastatin, atorvastatin and lovastatin
- Barbiturates, for anxiety, difficulty sleeping and epilepsy, such as phenobarbital
- Buspirone, for anxiety
- Midazolam, used as a sedative or anaesthetic
- Colchicine and sulfinpyrazone for gout
- Ritonavir, for HIV
- Almotriptan, used to treat migraine
- Anaesthetics, particularly those which are inhaled
- Dabigatran, to help prevent the formation of blood clots (anticoagulant)

Taking Vera-Til SR with food and drink and alcohol

- Do not drink grapefruit juice whilst taking Vera-Til SR as it can affect the absorption of this medicine.
- The consumption of alcohol should be avoided when taking Vera-Til SR.

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 for advice before taking this medicine.

Pregnancy

Vera-Til SR should not be given during the first 3 months (first trimester) of pregnancy unless your doctor has told you that it is safe to do so.

Breast-feeding

Vera-Til SR should not be taken if you are breast-feeding as it is passed into breast milk, unless your doctor has told you that it is safe to do so.

Driving and using machines

Vera-Til SR may influence your ability to drive, use machinery or work under hazardous conditions. If this happens, especially at the beginning of treatment or when increasing the dose, do not drive or operate machinery.

Vera-Til SR 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 Vera-Til SR

Always take Vera-Til SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Vera-Til SR should be taken orally
- Vera-Til SR should be swallowed whole with some liquid, preferably with or shortly after meals.
- Vera-Til SR tablets should not be chewed or crushed
- The score line is not intended for breaking the tablet

Adults:**High blood pressure (hypertension):**

- The usual dose is one 240mg Vera-Til SR tablet daily. Most patients respond to 240mg daily given as a single dose.
- If you are new to verapamil therapy, your doctor may prescribe half the usual dose, one Vera-Til SR tablet 120mg daily.
- A maximum dose of two Vera-Til SR 240mg tablets daily (one taken in the morning and one in the evening at an interval of about 12 hours) may be administered if control is not achieved within at least one week of treatment.
- Your doctor may prescribe other high blood pressure medicines in addition to Vera-Til SR if your blood pressure needs further reduction.

Chest pain (angina):

- The usual dose is one 240mg Vera-Til SR tablet twice a day.
- A few patients respond to a lower dose and where suitable, can take one 240mg Vera-Til SR tablet once a day.

Prevention of further heart attack:

- Treatment should commence at least one week after a heart attack.
- Vera-Til SR can be taken in divided doses either as 120mg three times daily, or as 240mg to be taken in the morning and 120mg to be taken in the evening on a daily basis.

Liver impairment:

In patients with impaired liver function, the effects of Vera-Til SR may be prolonged. Therefore, the dosage should be carefully adjusted and a low dose should be given initially.

Elderly:

The adult dose is recommended, except in patients with liver or kidney problems, where a reduced dose may be necessary.

After long-term treatment, your doctor may gradually discontinue your treatment with Vera-Til SR.

Use in children:

Vera-Til SR Tablets are not recommended for children and adolescents.

If you take more Vera-Til SR 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.

Symptoms of overdose include: fall in blood pressure, symptoms of shock, loss of consciousness, heart rhythm problems, increased blood sugar (hyperglycaemia), mental numbness (stupor), increased level of acid in the blood (metabolic acidosis) and acute respiratory distress syndrome.

If you forget to take your Vera-Til SR

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 Vera-Til SR

It is important that you keep taking Vera-Til SR for as long as your doctor has told you to.

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

4 Possible side effects

Like all medicines, Vera-Til SR can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Swelling of the deeper layers of the skin caused by a build-up of fluid (Quincke's oedema)
- Heart problems such as:
 - Slower (bradycardia), faster (tachycardia) or irregular heartbeat (arrhythmias), feeling your heartbeat (palpitations)
 - Swelling of the ankles, legs or feet (peripheral oedema)
 - Heart failure
 - Low blood pressure (hypotension)

- Severe blistering of the skin, mouth, eyes and genitals (Stevens–Johnson syndrome)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)

Rare side effects (may affect up to 1 in 1000 people)

- Flushing
- Unable to have an erection (impotence, erectile dysfunction)

Very rare side effects (may affect up to 1 in 10,000 people)

- Redness and swelling of the skin (erythema)
- Severe itching (pruritus)
- Skin rashes with the formation of wheals (urticaria)
- Liver problems such as an increase in liver enzymes (detected through blood test). Usually reversible after stopping the tablets
- Enlargement of the male breast—usually in elderly male patients (gynaecomastia). Usually due to long term treatment and reversible after stopping the tablets
- Enlargement of the gums (gingival hyperplasia). Usually due to long term treatment and reversible after stopping the tablets

Other side effects (frequency not known)

- Headache
- Dizziness
- Tingling or numbness in the hands or feet (paraesthesia)
- Shaking (tremor)
- Medicine-induced movement disorders (extrapyramidal syndrome)
- Feeling of dizziness or “spinning” (vertigo)
- Ringing in the ears (tinnitus)
- Feeling sick (nausea) or being sick (vomiting)
- Constipation
- Stomach pain
- Swelling of the ankle (oedema)
- Skin rash due to bleeding into the skin (purpura)
- Burning pain in the hands and/or feet which feel hot and are red in colour (erythromelalgia)
- Hair loss (alopecia)
- Muscle weakness
- Muscular pain (myalgia)
- Joint pain (arthralgia)
- Mental or physical tiredness (fatigue)
- Milky secretion from the breasts not due to breast-feeding (galactorrhoea)
- Increase in the level of the hormone prolactin (detected through blood test)

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 Vera-Til SR

- 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/blister after "EXP". The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original package.
- Medicines should not be disposed of 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 Vera–Til SR contains:

- Each 120mg modified release, film-coated tablet contains 120mg of verapamil hydrochloride.
- Each 240mg modified release, film-coated tablet contains 240mg of verapamil hydrochloride.

The other ingredients are: sodium alginate 80cP x H₂O, microcrystalline cellulose 90µm, povidone, magnesium stearate and colloidal anhydrous silica.

- The film coating for Vera–Til SR 120mg consists of lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000 and yellow ferric oxide (E172).

- The film coating for Vera-Til SR 240mg consists of lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000 and green varnish of quinoline yellow (E104) and indigotine (E132).

What Vera-Til SR looks like and contents of the pack:

- Vera-Til SR 120mg are round, beige to ochre, biconvex, modified release, film-coated tablets with a score on one side and an approximate diameter of 11mm.
- Vera-Til SR 240mg are oblong, light green, modified release, film-coated tablets with a score on both sides and an approximate diameter of 19mm.

Vera-Til SR is available in:

Vera-Til SR Tablets are available in packs of 28, 30, 56 or 100 tablets.

Not all pack sizes may be marketed.

Product Licence Numbers:

- Vera-Til SR 120mg Tablets: PL 11311/0077
- Vera-Til SR 240mg Tablets: PL 11311/0078

Marketing Authorisation Holder:

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
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United Kingdom

Manufacturers¹:

Kleva Pharmaceuticals S.A.
189, Parnithos Ave.
136 75 Acharnai - Attiki
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¹ Only actual manufacturer will be listed on printed leaflet