

Package leaflet: Information for the patient

Verisop 40 mg Film-coated Tablets Verisop 80 mg Film-coated Tablets Verisop 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 Verisop is and what it is used for
2. What you need to know before you take Verisop
3. How to take Verisop
4. Possible side effects
5. How to store Verisop
6. Contents of the pack and other information.

1. What Verisop is and what it is used for

Verisop contains verapamil hydrochloride which belongs to a group of medicines called calcium channel blockers. These medicines allow the blood vessels in the body and heart to relax and widen. In this way Verisop can

- help to reduce high blood pressure (hypertension)
- prevent or reduce angina (pain in the chest, neck or arm associated with exercise or stress)
- help treat an irregular or racing heart beat by slowing it down.

2. What you need to know before you take Verisop

Do not take Verisop

- if you are hypersensitive (allergic) to verapamil or any of the other ingredients of Verisop
- if you have recently suffered a heart attack
- if you have been told by your doctor that you suffer from heart block
- if you have an abnormally slow or irregular heart beat
- if you are already taking an intravenous beta-blocker to lower your blood pressure
- if you suffer from a condition called Wolf-Parkinson-White Syndrome
- if you are pregnant
- if you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and precautions

- if you know you have low blood pressure or suffer from a slow beating heart
- if you have heart failure or suffer from breathlessness and swollen ankles
- if you have liver or kidney disease.

Other medicines and Verisop

Please tell your doctor if you are taking any other medicines including medicines obtained without a prescription, herbal medicines or any of the following:

- medicines to lower blood pressure called beta-blockers, e.g. atenolol, metoprolol, propranolol
- prazosin and terazosin, to lower blood pressure or to treat prostate problems
- flecainide and quinidine, to treat irregular heart beat
- theophylline, for breathing problems
- medicines to treat epilepsy, e.g. phenobarbital, carbamazepine
- imipramine, to treat depression
- glyburide, to treat high blood sugar level
- medicines to treat gout, e.g. colchicine, sulfinpyrazone
- medicines to treat infections, e.g. erythromycin, rifampicin, telithromycin
- doxorubicin, to treat cancer
- medicines to treat anxiety, e.g. buspirone, midazolam
- digoxin, to treat a heart condition
- cimetidine, to treat heartburn or ulcers
- medicines to control the body's immune reactions, e.g. ciclosporin, everolimus, sirolimus, tacrolimus
- medicines to lower cholesterol, e.g. simvastatin, lovastatin, atorvastatin
- almotriptan, to treat migraine
- St. John's Wort, to treat depression
- antiviral medicine, e.g. ritonavir
- lithium, to treat mental illness
- medicines used to relax muscles
- aspirin, to relieve pain and inflammation

Ask your doctor for advice before taking any medicine.

Verisop with food and drink

Do not take Verisop with grapefruit juice as this can alter the effect of this medicine.

Do not drink alcohol while taking this medicine, as you may notice an increase in the side effects of Verisop.

Pregnancy and breast-feeding

Do not take Verisop if you are pregnant or breast-feeding your baby, unless advised by your doctor.

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

Driving and using machines

Do not drive or use machines if Verisop affects your ability to do these tasks.

Verisop contains lactose

If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Verisop

Always take Verisop exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a glass of water with or shortly after meals. Do not take with grapefruit juice.

The dose of Verisop will depend on the condition being treated. The usual doses are:

ADULTS only

Angina, including Prinzmetal angina:

The usual dose is 120mg of Verisop, 3-4 times daily. Some patients are managed on a smaller dose of 80mg Verisop 3 times daily.

Irregular heart beat or rhythm:

The usual dose is 40mg to 120mg of Verisop 3-4 times daily depending on the severity of the condition.

Hypertension (high blood pressure):

The usual dose is 40mg to 120mg of Verisop 3-4 times daily. In long-term treatment a daily dose of 480mg should not be exceeded.

If you suffer from liver or kidney disease, your doctor may prescribe lower doses of Verisop than the above, to treat your condition.

If you take more Verisop than you should

If you take more Verisop than you should contact your doctor or hospital emergency department immediately.

If you forget to take Verisop

If you forget to take a dose of Verisop take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Verisop

Do not stop taking Verisop without talking to your doctor first.

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.

The side effects include:

- constipation
- feeling or being sick
- stomach pain or discomfort
- feeling tired or dizzy
- tremor
- ringing in the ears
- involuntary, irregular muscle movements
- restlessness
- hair loss
- tingling
- painful burning sensation in the extremities
- muscle weakness
- joints and muscles pain
- flushing
- headache
- swelling of the ankles
- yellowing of the skin or whites of the eyes
- dark urine and pale stools
- impotence
- unusual secretion of breast milk

Sometimes, Verisop can cause your blood pressure to drop too low and your heart beat to become slow or fast and irregular. Also you can develop shortness of breath and swelling of the feet or legs. Tell your doctor if this happens to you.

If you have a heart condition and you feel your symptoms are getting worse, speak to your doctor.

Allergic reactions such as itchy, red skin may occur. Serious allergic reactions, which cause swelling of the face or the throat, severe skin reactions, blistering of the skin, mouth, eyes and genitals, may occur.

Also swelling of the gums and breast enlargement in men may occur but these side effects go away on stopping treatment.

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; 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 Verisop

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store tablets in the original package.

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 Verisop contains

- The active substance is 40mg, 80mg or 120mg of verapamil hydrochloride.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, pregelatinised maize starch, sodium starch glycolate, purified talc and magnesium stearate. The tablet coating contains diethyl phthalate, carnauba wax, hypromellose (E464), opadry white Y-1-7000 (consisting of titanium dioxide (E171), hypromellose and macrogol 400).

What Verisop looks like and the contents of the pack

Your medicine comes as a white coated tablet. The 40mg tablet is marked 'VL/40'; the 80mg tablet 'VL/80' and the 120mg tablet 'VL/120'. All tablets have a 'G' on the other side.

Verisop is available in plastic bottles of 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Generics [UK] Limited, Station Close, Potters Bar, Herts EN6 1TL, UK.

Manufacturer

McDermott Laboratories Limited,
T/A Gerard Laboratories,
35/36 Baldoye Industrial Estate, Grange Road,
Dublin 13, Ireland.

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