

Package leaflet: Information for the patient

VEPROL

Film-coated tablets – 40 mg or 80 mg

(Verapamil hydrochloride)

Read this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Veprol is and what it is used for
2. Before you take Veprol
3. How to take Veprol
4. Possible side effects
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6. Other information

1. WHAT VEPROL IS AND WHAT IT IS USED FOR

Veprol contains the active substance verapamil hydrochloride.

Verapamil is a calcium channel blocker. The mechanism of action consists in inhibiting the entrance of calcium into the cell. Verapamil acts in smooth muscle, myocardial cells, and cells within the sino-atrial and atrioventricular nodes. The main actions of the calcium-channel blockers include dilation of coronary and peripheral arteries and arterioles. Verapamil causes slowing of atrioventricular conduction, reduction of heart rate and a negative inotropic action.

Verapamil is used in the treatment of:

- supraventricular arrhythmias;
- angina pectoris;
- hypertension.

2. BEFORE YOU TAKE VEPROL

Do not take Veprol if you:

- are hypersensitive to verapamil or to any of the excipients of Veprol;
- have hypotension, bradycardia, second- and third-degree AV block, sick sinus syndrome, cardiogenic shock, sino-atrial block;
- have a history of heart failure or significantly impaired left ventricular function, even if controlled by therapy;
- have atrial flutter or fibrillation associated with accessory conducting pathways (e.g. Wolff-Parkinson-White syndrome);
- have acute porphyria;
- are on concomitant treatment with ivabradine.

Take special care with Veprol

Ask your doctor before you take Veprol.

Veprol should be used with caution in first-degree AV block, acute phase of myocardial infarction and in patients taking beta-blockers (should only be used if myocardial function is well preserved).

Verapamil should be avoided in the first trimester of pregnancy, unless absolutely necessary.

Sudden withdrawal of verapamil might be associated with exacerbation of angina.

Doses of verapamil should be reduced in patients with hepatic impairment.

Avoid concomitant ingestion of grapefruit juice.

Taking other medicines

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

It is particularly important to inform your doctor that you are taking:

- general anesthetics because they enhance the hypotensive effect of verapamil;
- amiodarone, disopyramide or flecainide, dronedarone (anti-arrhythmics);
- clarithromycin, erythromycin, rifampicin (antibiotics);
- dabigatran etexilate (anticoagulant);
- monoamine oxidase inhibitors (MAOI), buspirone, lithium, St. John's wort, tricyclics (drugs against depression, anxiety and psychosis);
- carbamazepine, phenytoin, primidone (antiepileptic drugs);
- atazanavir, cobicistat (antivirals);
- midazolam (hypnotic drug);
- barbiturates, because they reduce the effect of verapamil;
- beta-blockers because they increase the risk of asystole, severe hypotension and heart failure;
- alpha blockers (prazosin and terazosin);
- digoxin (cardiac glycoside);
- colchicine (drug used for the treatment of gout), because verapamil possibly increases the risk of colchicine toxicity; avoid concomitant use in hepatic or renal impairment;
- eplerenone (diuretic);
- dutasteride (hormone antagonist);
- ciclosporin, everolimus, sirolimus and tacrolimus (immunosuppressants);
- ivabradine, because verapamil increases the plasma concentration of ivabradine; avoid concomitant use;
- simvastatine, atorvastatine (drugs that lower cholesterol levels in the blood);
- theophylline (drug used in asthma);
- dantrolen;
- cimetidine (medicine to treat stomach ulcers);
- aspirin (for pain, fever or to prevent blood clots);
- idelalisib, topotecan (medicines to treat cancer);
- glibenclamide, (used to treat certain types of diabetes);
- metformin, (verapamil may decrease the glucose-lowering effect of metformin).

Taking Veprol with food and drinks

Do not drink grapefruit juice whilst taking Veprol as it can increase the blood concentration of verapamil.

It is not recommended to consume alcohol while you are taking Veprol because it increases the plasma concentration of alcohol.

Pregnancy

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The use of verapamil in pregnancy may reduce uterine blood flow with fetal hypoxia. It should be avoided in the first trimester, unless absolutely necessary. Also it may inhibit labour.

Breastfeeding

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Several studies have shown that verapamil is excreted into breast milk in small amounts and is unlikely to be harmful. However, it is not recommended to be used during breastfeeding, unless the doctor considers necessary its use.

Driving and using machines

Veprol can cause dizziness, fatigue, sleepiness and equilibrium disorders, affecting the ability of driving or using machines. It is recommended to avoid the use of Veprol while driving or using machines, especially when you consume alcohol, because verapamil increases the blood level of alcohol and so the effects of alcohol may be exaggerated.

3. HOW TO TAKE VEPROL

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

Adults

Supraventricular arrhythmias: 40 – 120 mg, 3 times daily.

Angina pectoris: 80 – 120 mg, 3 times daily.

Hypertension: 240 – 480 mg daily in 2 –3 divided doses.

If you take more Veprol than you should

If you take more Veprol than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

Overdosage of oral verapamil produces symptoms that are mainly extensions of common adverse reactions. Hypotension, bradycardia, AV block or asystole and fatalities have been reported in patients with verapamil overdosage.

Treatment: All overdosages of verapamil should be considered serious; patients should be observed for at least 48 hours and preferably in a hospital setting. It is recommended gastric lavage and administration of intravenous fluids. Verapamil is not removed by haemodialysis.

If you forget to take Veprol

If you forget taking one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose to make up a forgotten dose.

If you stop taking Veprol

Sudden withdrawal of verapamil might be associated with exacerbation of angina.

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

4. POSSIBLE SIDE EFFECTS

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

Treatment with verapamil is generally well tolerated, but adverse effects connected with its pharmacological effects on cardiac conduction can arise and may be particularly severe in patients with previous myocardial damage or hypertrophic cardiomyopathies. Adverse effects on the heart include bradycardia, atrioventricular block, worsening heart failure and transient asystole. These effects are more common with parenteral than with oral therapy.

The most troublesome non-cardiac adverse effect is constipation. Nausea may occur but is less frequently reported. Other side effects include ileus and abdominal discomfort.

Adverse effects on musculoskeletal and connective tissue include muscular weakness, myalgia and arthralgia.

Adverse effects on ear and labyrinth include vertigo, tinnitus.

Other adverse effects include hypotension, dizziness, flushing, headaches, paraesthesia, tremor, extrapyramidal syndrome (e.g. parkinsonism), dystonia, fatigue, dyspnoea and peripheral oedema.

There have been reports of skin reactions (alopecia, Quincke's oedema, Stevens-Johnson syndrome, erythema multiforme, erythromelalgia, purpura, pruritus, urticaria and some cases of abnormal liver function and hepatotoxicity, gingival hyperplasia. Gynaecomastia and impotence (erectile dysfunction) have been reported rarely.

If you get these side effects or any side effect not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE VEPROL

Keep out of the sight and reach of children!

Do not use Veprol after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package.

6. OTHER INFORMATION

What Veprol 40 mg or 80 mg film-coated tablets contain:

The active substance is verapamil hydrochloride.

Each film-coated tablet contains 40 mg or 80 mg verapamil hydrochloride.

The excipients are:

tablet core: microcrystalline cellulose, croscarmellose sodium, pregelatinized starch, colloidal anhydrous silica, magnesium stearate

film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc, red iron oxide, yellow iron oxide.

Contents of the pack:

Veprol 40 mg Film-coated tablets:

Carton box with 30 film-coated tablets.

Veprol 80 mg Film-coated tablets:

Carton box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.

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