

VASILIP TABLET

Simvastatin (10 mg & 20 mg)

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What Vasilip is used for

Vasilip is used along with diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia).
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.
- coronary heart disease (CHD) or are at high risk of CHD (because you have diabetes, history of stroke, or other blood vessel disease). Vasilip may reduce the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

How Vasilip works

Vasilip is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, Vasilip raises levels of "good" cholesterol (HDL cholesterol). You should stay on cholesterol-lowering diet while taking this medicine. Vasilip is a member of the class of drugs called statins.

Before you use Vasilip

When you must not use it

- if you are allergic (hypersensitive) to simvastatin or any of the other ingredients of Vasilip tablets
- if you currently have liver problems
- if you are pregnant or breast-feeding
- if you are taking one or more than one of the following drugs at the same time:
 - o itraconazole, ketoconazole, posaconazole or voriconazole (medicines for fungal infections)
 - o erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
 - o HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
 - o boceprevir or telaprevir (medicines for hepatitis C virus infection)
 - o nefazodone (a medicine for depression)
 - o gemfibrozil (a medicine for lowering cholesterol)
 - o ciclosporin (a medicine often used in organ transplant patients)
 - o danazol (a man-made hormone used to treat endometriosis (endometrium is found growing in other areas outside of the uterus)).

Pregnancy and lactation

Do not take Vasilip if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking

Vasilip, stop taking it immediately and contact your doctor. Do not take Vasilip if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

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

Before you start to use it

- Tell your doctor about all your medical conditions including allergies.
- Tell your doctor if you drink large amounts of alcohol.
- Tell your doctor if you have ever had liver disease. Vasilip may not be right for you.
- Tell your doctor if you are due to have an operation. You may need to stop taking Vasilip tablets for a short time.
- Your doctor should do a blood test before you start taking Vasilip and if you have any symptoms of liver problems while you take Vasilip. This is to check how well your liver is working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Vasilip.
- While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.
- Tell your doctor if you have severe lung disease.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle

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breakdown resulting in kidney damage; and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of Vasilip, particularly the 80-mg dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- you consume large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called "statins" or fibrates
- you or a close family member have a hereditary muscle disorder.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

It is particularly important to tell your doctor if you are taking any of the following drugs. Taking Vasilip with any of these drugs can increase the risk of muscle problems:

- ciclosporin (a medicine often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis)
- medicines like itraconazole, ketoconazole, fluconazole, or posaconazole (medicines for fungal infections)
- fibrates like gemfibrozil and bezafibrate (medicines for lowering cholesterol)
- erythromycin, clarithromycin, telithromycin, or fusidic acid (medicines for bacterial infections)

- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS)
- boceprevir or telaprevir (medicines for hepatitis C virus infection)
- nefazodone (a medicine for depression)
- amiodarone (a medicine for an irregular heartbeat)
- verapamil, diltiazem or amlodipine (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)
- colchicine (a medicine used to treat gout).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:

- medicines to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrate (another medicine for lowering cholesterol)
- niacin (another medicine for lowering cholesterol)
- rifampicin (a medicine used to treat tuberculosis).

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

How to use Vasilip

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the

instructions on the label, ask your doctor or pharmacist for help.

The dose is 1 Vasilip 10 mg, 20 mg, 40 mg, or 80 mg tablet by mouth once a day. For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

The 80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.

The usual starting dose is 10, 20 or, in some cases, 40 mg a day. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. Do not take more than 80 mg a day. Your doctor may prescribe lower doses, particularly if you are taking certain medicinal products listed above or have certain kidney conditions. Keep taking Vasilip unless your doctor tells you to stop.

If your doctor has prescribed Vasilip along with any bile acid sequestrant (medicines for lowering cholesterol), you should take Vasilip at least 2 hours before or 4 hours after taking the bile acid sequestrant.

When to use it

Use as directed by your doctor or pharmacist. Take Vasilip in the evening. You can take it with or without food.

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How long to use it

Continue taking Vasilip for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Do not take an extra dose; just take your normal amount of Vasilip at the usual time the next day.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Vasilip.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Vasilip to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

Vasilip is not expected to interfere with your ability to

drive or to use machinery. However, it should be taken into account that some people get dizzy after taking Vasilip. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10,000 patients treated).
- Frequency not known

The following rare serious side effects were reported.

If any of these serious side effects happen, stop taking the medicine and tell your doctor immediately or go to the emergency room at your nearest hospital.

- muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle

problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred.

- hypersensitivity (allergic) reactions including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing
 - severe muscle pain
 - pain or inflammation of the joints
 - inflammation of the blood vessels
 - unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, flushing
 - shortness of breath and feeling unwell
 - lupus-like disease picture (including rash, joint disorders, and effects on blood cells)
 - inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite; liver failure (very rare)
 - inflammation of the pancreas often with severe abdominal pain.

The following side effects have also been reported rarely:

- low red blood cell count (anaemia)
- numbness or weakness of the arms and legs
- headache, tingling sensation, dizziness
- digestive disturbances (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- rash, itching, hair loss
- weakness
- trouble sleeping (very rare)
- poor memory (very rare), memory loss, confusion.

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The following side effects have also been reported but the frequency cannot be estimated from the available information (frequency not known):

- erectile dysfunction
- depression
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever
- tendon problems, sometimes complicated by rupture of the tendon.

Additional possible side effects reported with some statins:

- sleep disturbances, including nightmares
- sexual difficulties
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Laboratory Values

Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatin kinase) have been observed.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Vasilip

Storage

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Store in the original package. Do not use your medicine after the expiry date which is stated on

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

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

10 mg tablet: Round, slightly biconvex, bevel edged, white film coated tablets.

20 mg tablet: Round, slightly biconvex, bevel edged, white film coated tablets.

Ingredients

Active ingredients

Each film-coated tablet contains 10 or 20 mg of simvastatin.

Inactive ingredients

Lactose monohydrate, pregelatinised starch, butylhydroxyanisole, anhydrous citric acid, ascorbic acid, maize starch, microcrystalline cellulose and magnesium stearate in the tablet core, and hypromellose, talc, propylene glycol and titanium dioxide (E171) in the film-coating.

MAL number:

10 mg: MAL 05121159A

20 mg: MAL 05121160A

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai, 5 ½
Miles off Jalan Meru, 41050
Klang, Selangor, MALAYSIA.

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