

COVASTIN TABLET

Simvastatin (10mg, 20mg, 40mg)

What is in this leaflet

1. What Covastin is used for
2. How Covastin works
3. Before you use Covastin
4. How to use Covastin
5. While you are using it
6. Side effects
7. Storage and Disposal of Covastin
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What Covastin is used for

It is used to treat high cholesterol levels and helps to reduce risk of heart disease problems (coronary heart disease (CHD)). If you have CHD, diabetes, history of stroke, or other vessel disease (regardless of the amount of cholesterol in your blood), COVASTIN:

- a. can prolong your life by reducing the risk of heart attack or stroke
- b. reduces the need for surgery to increase blood flow to the legs and major organs such as the heart
- c. reduces the need for hospitalization for chest pain (called angina).

How Covastin works

Simvastatin is the drug classified as statins. It works by blocking HMG-CoA enzyme that involves in cholesterol production. Therefore, less cholesterol is made and reduces cholesterol levels in the blood. Simvastatin lowers the level of total cholesterol, 'bad' cholesterol (LDL, low density lipoprotein) and fatty substances called triglycerides. It raises 'good' cholesterol (HDL, high density lipoprotein).

Before you use Covastin

- When you must not use it

Do not take Covastin if you:

- have acute liver disease.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to start breast-feeding.
- taking potent CYP3A4 inhibitors, gemfibrozil, ciclosporin or danazol.
- have homozygous familial hypercholesterolaemia and taking lomitapide with more than 40mg simvastatin dose.

- are allergic (hypersensitive) to Simvastatin or any ingredients in this medicine.

- Before you start to use it

Tell your doctor or pharmacist:

- If you are allergic (hypersensitivity) to simvastatin or any other ingredients in this medicine.
- If you are pregnant or plan to become pregnant.
- If you are breast-feeding or plan to start breast-feeding.
- If you have ever been told that you have problems with your kidneys.
- If you have ever been told that you have problems with your liver.
- If you have had unexplained muscle aches or pains, a history of muscle pains, or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol.
- If you take other medicines called fibrates to lower your cholesterol.
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir
- If you have high blood sugar or raised HbA1c.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease-causing eye muscle weakness) as statins may sometimes aggravate the condition.

Do not take Covastin if you are pregnant, trying to become pregnant or suspect that they are pregnant.

Do not take Covastin if you are breast-feeding.

- Taking other medicines

Do not take Covastin together with:

- Potent CYP3A4 inhibitors such as Itraconazole, Ketoconazole, Posaconazole, Voriconazole, Erythromycin, Clarithromycin, Telithromycin, HIV protease inhibitors (e.g., nelfinavir), Boceprevir, Telaprevir, Nefazodone, Cobicistat, Ciclosporin, Danazol, Gemfibrozil.
- Other fibrates (except fenofibrate).

- Niacin (nicotinic acid) ($\geq 1\text{g/day}$).
- Amiodarone, Amlodipine, Verapamil, Diltiazem, Elbasvir, Grazoprevir.
- Lomitapide.
- Daptomycin.
- Grapefruit juice.

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

How to use Covastin

- How much to use

- Take Covastin exactly as your doctor tells you to take it.
- For adults, the recommended usual starting dose is 20-40 mg a day, given as a single dose in the evening. Your doctor may adjust your dose to a maximum of 80 mg a day, given as a single dose in the evening. Because of the increased risk of muscle problems, the 80-mg dose is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
- For children (10-17 years old), the recommended usual starting dose is 10 mg a day, given as a single dose in the evening. The maximum recommended dose is 40 mg a day.
- Your doctor may prescribe lower doses, particularly if you are taking certain of the medications listed above or have certain kidney conditions. Keep taking Covastin unless your doctor tells you to stop. If you stop taking Covastin, your cholesterol may rise again.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your

next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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

There is no specific treatment in the event of overdose. In this case, symptomatic and supportive measures should be adopted.

While you are using Covastin

- Things you must do
 - Swallow each tablet whole with a drink of water.
 - Try to take your tablet at the same time every day to help you to remember to take it.

Tell all the doctors, dentists and pharmacists treating you that you are using Covastin.
Take Covastin only with a doctor's prescription.

- Things you must not do
 - Do not stop using the medicine unless advised by your doctor.
 - Do not use any new medicines without consulting your doctor or pharmacist.
 - Do not give Covastin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizzy do not drive or use machines and contact your doctor immediately.

Side effects

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

Possible side effects are:

- Gastrointestinal disturbances
- Headache/ dizziness.

- Increased in serum aminotransferase.
- Muscle pain and weakness.
- Myasthenia gravis (a disease-causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease-causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after period of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

If you have muscle problems that do not go away after your doctor has told you to stop taking Covastin, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Covastin

- Storage
Store below 30°C.
Keep out of the reach of the children.
Do not use this medicine after expiry date.
- 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
Covastin Tablet 10mg:
Peach coloured round shape film-coated tablet, with 'XS' marking and breakline on one side and plain on reverse.
Available as blister pack of 10's in packing of 30's per box.

Covastin Tablet 20mg:
Pink coloured pentagon shape film coated tablet, with marking "XS" and breakline on one side and plain on reverse.

Available as blister pack of 10's in packing of 30's and 100's per box.

Covastin Tablet 40mg:

Brick red coloured pentagon shape film coated tablet, with "XS" marking and breakline on one side and plain on reverse.

Available as blister pack of 10's in packing of 30's and 100's per box.

- Ingredients

- Active ingredient(s)
 - Simvastatin

- Inactive ingredients
Citric Acid, Ascorbic Acid, Microcrystalline Cellulose, Starch, Lactose Monohydrate, Butylated Hydroxyanisole, Magnesium Stearate, Purified Water and Isopropyl Alcohol, Hydroxypropyl Methylcellulose Compound Mix (for Covastin Tablet 10mg, 20mg, 40mg), Pigment Red Colour (for Covastin Tablet 10mg, 20mg, 40mg), Pigment Yellow Color (for Covastin Tablet 10mg)

- MAL number(s):

- Covastin Tablet 10mg:
MAL23016008AZ
- Covastin Tablet 20mg:
MAL23016009AZ
- Covastin Tablet 40mg:
MAL22076004AZ

Manufacturer

Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate,
75250 Melaka, Malaysia.

Product Registration Holder

GoodScience Sdn. Bhd.
No. 7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya, 48020 Rawang,
Selangor, Malaysia.

Date of revision

19 February 2026

Serial Number

NPRA(R2/1)250911/01540