

# SIMVAHEXAL<sup>®</sup> FILM-COATED TABLET

Simvastatin (10mg, 20mg)

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## What SimvaHEXAL is used for

SimvaHEXAL helps to lower cholesterol and triglyceride levels in your blood.

SimvaHEXAL is used in addition to your cholesterol-lowering 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). SimvaHEXAL may prolong your life by reducing the risk of heart disease problems, regardless of the amount of cholesterol in your blood.

## How SimvaHEXAL works

SimvaHEXAL contains the active ingredient Simvastatin, which belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. It reduces 'bad' (LDL) cholesterol and plasma triglyceride while raises the 'good' (HDL) cholesterol.

SimvaHEXAL affects only the cholesterol and triglycerides made by the liver in your body. It has no effect on cholesterol and triglycerides that come from fats in food. Therefore, when you are taking SimvaHEXAL, you also need to follow a low fat diet and other measures, such as exercise and weight control.

In most people, there are no symptoms of high cholesterol or triglycerides. Your doctor

can measure your cholesterol and triglycerides with a simple blood test.

## Before you use SimvaHEXAL

### - When you must not use it

Do not take SimvaHEXAL if you:

- are allergic to simvastatin or any other ingredients of this medicine (listed in Product Description).
- are pregnant or breastfeeding.
- have liver problems.
- have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

*If you are not sure whether you should start taking SimvaHEXAL, talk to your doctor.*

### - Before you start to use it

Tell your doctor if you have allergies to any other medicines or any other substances, including foods, preservatives or dyes.

Tell your doctor or pharmacist if you:

- intend to become pregnant or breastfeed. SimvaHEXAL should not be used during pregnancy or while breastfeeding.
- have ever had liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
- have kidney disease or any other medical problems.
- have severe breathing problems.
- drink large amounts of alcohol.
- have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Your doctor may do a blood test to check for certain muscle problems.
- are due to have an operation. You may need to stop taking this medicine for a short time.
- are Asian, because a different dose may be applicable to you.
- have or have had myasthenia gravis (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.

Your doctor should do a blood test before you start taking SimvaHEXAL and if you have any symptoms of liver problems while

you take this medicine. 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 this medicine.

### Pregnancy and lactation

Do not take SimvaHEXAL if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking SimvaHEXAL, stop taking it immediately and contact your doctor.

Do not take SimvaHEXAL if you are breastfeeding, because it is not known if the medicine is passed into breast milk.

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

### Children and Adolescents

Safety and effectiveness of simvastatin have been studied in 10-17 years old boys and in girls, who had started their menstrual period at least one year before. Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

### - Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription from your pharmacy, supermarket or health food shop, including herbal medicines.

Some medicines must not be taken with SimvaHEXAL as they may increase the risk of muscle problems. It is particularly important to tell your doctor if you are taking:

- Other medicines to lower cholesterol levels, such as fibrates (e.g. fenofibrate, gemfibrozil), niacin (doses higher than 1g daily) or other medicines in statin's group (e.g. lovastatin, atorvastatin)
- Antifungal agents (e.g. itraconazole, ketoconazole, posaconazole or voriconazole)
- HIV protease inhibitors (e.g. nelfinavir)
- Hepatitis C antiviral agents (e.g. boceprevir, telaprevir, elbasvir or grazoprevir)
- Antibiotics used to treat infections (e.g. erythromycin, clarithromycin, telithromycin or fusidic acid)

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- Nefazodone (used to treat depression)
- Cyclosporin (often used to suppress the immune system in organ transplant patients)
- Danazol (used to treat endometriosis or fibrocystic breast disease)
- Verapamil, diltiazem or amlodipine (used to treat high blood pressure, angina or other heart conditions)
- Amiodarone (treat irregular heartbeat)
- Colchicine (used to treat gout)
- Medicines containing cobicistat (used in the treatment of HIV infection)
- Lomitapide (used to treat a serious and rare genetic cholesterol condition)
- Daptomycin (used to treat complicated skin and skin structure infections and bloodstream infections)
- Oral anticoagulant (to prevent blood clots)
- Rifampicin (used to treat tuberculosis)
- Ticagrelor (antiplatelet medicine)

These medicines may be affected by SimvaHEXAL, may affect how well it works, or may increase the risk of side effects with SimvaHEXAL. You may need different amounts of your medicine, or you may need to take different medicines.

## How to use SimvaHEXAL

Your doctor will tell you how many tablets you need to take each day. This depends on your cholesterol and triglyceride levels and other factors, such as kidney disease. Take your medication exactly as directed by your doctor. Check with your doctor or pharmacist if you are not sure.

You should stay on a cholesterol-lowering diet while taking SimvaHEXAL.

### - How much to use

#### • Adults

The recommended starting dose is 20 or 40mg a day, given as a single dose in the evening. Your doctor may adjust your dose after at least 4 weeks to a maximum of 80mg a day. Do not take more than 80mg a day.

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.

#### • Children and Adolescents (10-17 years old)

The recommended usual starting dose is 10mg a day in the evening. The maximum recommended dose is 40mg a day.

Your doctor may prescribe lower doses, particularly if you are taking certain medications listed above or have certain kidney conditions.

### - When to use it

SimvaHEXAL is recommended to be taken once a day in the evening.

The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people this is at night when asleep. Therefore, this medicine is more effective when taken in the evening. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.

Taking SimvaHEXAL at about the same time each evening will have the best effect. It will also help you remember when to take the tablets.

### - How long to use it

Continue taking your medicine for as long as your doctor tells you.

SimvaHEXAL helps lower your cholesterol but does not cure your condition. You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking SimvaHEXAL, your cholesterol levels may rise again.

### - 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 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 SimvaHEXAL

### - Things you must do

- Always follow the instructions given to you by your doctor or pharmacist.
- Inform all the doctors, dentists and pharmacists treating you that you are taking SimvaHEXAL.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SimvaHEXAL.
- If you become pregnant while taking SimvaHEXAL, stop taking it and contact your doctor immediately.
- If you are about to have elective surgery, tell the surgeon or anaesthetist that you are taking SimvaHEXAL. Your doctor may suggest stopping this medicine a few days before surgery.
- Keep all your doctor's appointments so that your progress can be checked. Your doctor may request some tests to check your blood cholesterol levels to make sure the medicine is working properly, and to prevent unwanted side effects.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.

### - Things you must not do

- Do not stop taking SimvaHEXAL unless advised by your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

### - Things to be careful of

Avoid drinking large quantities of alcohol. Drinking large quantities of alcohol may increase your chance of SimvaHEXAL causing liver problems.

Grapefruit juice should be avoided while taking SimvaHEXAL. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including SimvaHEXAL.

### *Driving and using machines*

Be careful driving or operating machinery until you know how this medicine affects you. If you feel dizzy after taking this medicine, do not drive, or operate machinery or do anything else that could be dangerous.

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## Side effects

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

## Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any of the following:

- Unexplained muscle problems such as muscle pain, tenderness, weakness, especially muscle weakness that is constant, muscle rupture or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred. The risk of muscle breakdown is greater for:

- patients taking higher doses of simvastatin, particularly the 80-mg dose
- older patients (65 years of age and older)
- female patients

- patients with abnormal kidney function
- patients with thyroid problems

- Allergic reactions including:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- shortness of breath and feeling unwell

- 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

- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)

- Inflammation of the liver with yellowing of the skin and eyes, itching, feeling tired or weak, loss of appetite, dark-coloured urine or pale-coloured stool, which may lead to liver failure

- Inflammation of the pancreas often with severe abdominal pain

- Inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever

The following side effects have also been reported:

- Signs of anaemia, such as tiredness, being short of breath, and looking pale

- Headache, dizziness

- Tingling in the hands or feet

- Blurred vision, impaired vision

- Stomach upset or pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting

- Painful, swollen joints

- Skin rash, itchiness

- Hair loss

- Trouble sleeping

- Poor memory, memory loss, confusion

- Erectile dysfunction

- Depression

- Larger breasts than normal in men

- 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 periods 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 even after your doctor has told you to stop taking SimvaHEXAL, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Elevations in some laboratory blood tests of liver function and a muscle enzyme (creatine kinase) have been observed. Increases in fasting blood sugar have also been reported with this group of medicines.

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

## Storage and Disposal of SimvaHEXAL

- Storage

Do not store above 30°C.

Keep blisters in the outer carton in order to protect from light.

Keep all medicines out of sight and reach of children.

- 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

**SimvaHEXAL 10mg:** Pale pink coated, oval, scored, convex tablet coded SIM 10 on one side.

**SimvaHEXAL 20mg:** Orange coated, oval, scored, convex tablet coded SIM 20 on one side.

- Ingredients

- Active ingredient

**SimvaHEXAL 10mg:** Each tablets contains 10mg Simvastatin.

**SimvaHEXAL 20mg:** Each tablets contains 20mg Simvastatin.

- Inactive ingredients

Pregelatinized starch, lactose monohydrate, microcrystalline cellulose, butylhydroxy-anisole, ascorbic acid, magnesium stearate, citric acid monohydrate, hypromellose, talc, titanium dioxide, red ferric oxide, yellow ferric oxide

- MAL Number

SimvaHEXAL 10mg (MAL11100001ARZ)

SimvaHEXAL 20mg (MAL11100002ARZ)

## Manufacturer

Sandoz Grup Saglik Urunleri

Ilaclari Sanayi ve Ticaret A.S.

GOSB Ihsan Dede Cad. 900. sok.

TR-41400 Gebze-Kocaeli, Turkey.

## Product Registration Holder

IMEKS Pharma Sdn. Bhd.

No. 5 & 9, Jalan Undang Harimau 2,

Medan Niaga Kepong,

51200 Kuala Lumpur, Malaysia.

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28/11/2025

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