

## WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about **Simvahexal**. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet, you may need to read it again.

### 1. WHAT IS **Simvahexal** USED FOR

**Simvahexal** is used to lower high cholesterol and triglyceride levels. It is used in people who have high blood cholesterol level. **Simvahexal** may also be used to reduce the risk of heart disease in patients suffering from the hardening of the arteries or diabetes.

### 2. HOW DOES **Simvahexal** WORKS

**Simvahexal** contains the active ingredient simvastatin, which belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. **Simvahexal** reduces the 'bad' cholesterol and plasma triglyceride while raises the 'good' 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, **Simvahexal** treatment should be accompanied by a diet that is low in fat.

### 3. BEFORE YOU TAKE **Simvahexal**

#### **Do not take this medicine if**

- you are allergic to the active ingredient or any ingredients in the formulation or any other similar medicines.
- you have liver problems
- you are pregnant
- you experience muscle pain when using other cholesterol lowering medicines.
- you are using the following medicines:

- itraconazole, ketoconazole (antifungal agent)
- HIV-protease inhibitors,
- erythromycin, clarithromycin, telithromycin (antibiotics)
- nefazodone (immunosuppressant)

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

#### **Before you start taking this medicine**

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

Tell your doctor if you have or have had any medical conditions, especially:

- liver disease
- kidney disease
- personal or hereditary muscular disorder
- previous history of muscular toxicity with a statin or fibrate (other cholesterol lowering medicines)
- any unexplained muscle pain tenderness and weakness
- uncontrolled hypothyroidism
- alcohol abuse
- underwent or going to have surgery

#### **Taking other medicines**

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription.

These medicines may be affected by **Simvahexal**, or may affect how well it works. You may need different amount of your medicines, or you may need to take different medicines. Inform your doctor or pharmacist if you are taking the following:

- other medicines to lower blood cholesterol level such as fibrates (e.g. fenofibrate, gemfibrozil) or other medicine in statin's group (eg. lovastatin, atorvastatin)
- more than 1g niacin (vitamin B3) per day
- antifungal agents, e.g itraconazole and ketoconazole
- antibiotics, e.g erythromycin, clarithromycin and telithromycin

- medicines for HIV patients, eg: saquinavir, ritonavir, indinavir, nelfinavir, amprenavir.
- nefazodone, an antidepressant
- ciclosporin, an immunosuppressant
- danazol, used in the treatment of menstrual pain
- amiodarone, for treatment of irregular heart beat
- verapamil and diltiazem, to lower blood pressure
- oral anticoagulant, e.g: warfarin
- alcohol
- grapefruit juice

#### **Pregnancy and lactation**

Simvastatin should not be taken during pregnancy or breastfeeding. If you are pregnant or plan to breastfeed while taking this medicine, consult your doctor immediately.

### 4. HOW TO TAKE **Simvahexal**

Take your medication exactly as directed by your doctor.

#### **Adult**

##### **How much to take:**

5 – 80 mg daily taken in the evening. Your doctor may decide to adjust your dose after 4 weeks or more.

##### **High blood cholesterol level:**

The usual starting dose is 20-40 mg/day given as a single dose in the evening together with standard cholesterol-lowering diet.

##### **High blood cholesterol level due to hereditary factor:**

Treatment with **Simvahexal** can be initiated with the following dosage regimen:

- 40 mg/day in the evening *or*
- 80 mg/day in 3 divided doses of 20 mg, 20 mg, and an evening dose of 40 mg.

**Simvahexal** is to be used together with other cholesterol lowering treatments.

##### **Prevention of cardiovascular disease:**

The usual dose of simvastatin is 40 mg/day given as a single dose in the evening.

**How to take:**

Swallow the tablet with a glass of water.

**When to take:**

Single dose should be taken in the evening; divided dose can be taken in the morning, afternoon and evening.

**How long to take it**

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is very important that you do not stop taking this medicine suddenly.

**If you forget to take it**

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

**If you take too much**

If you or anyone else takes too many tablets, tell your doctor or go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

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## 5. WHILE YOU ARE USING *Simvahexal*

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**Things you must do**

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking *Simvahexal*
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- Check your cholesterol level when directed to ensure that this medicine is working for you.
- Your doctor might perform blood tests to check your liver functions.
- Inform your doctor if you experience muscle pain, weakness or cramps.
- Inform your doctor if you experience abdominal pain, nausea dan vomiting.

- Inform your doctor if you are pregnant while taking *Simvahexal*

**Things you must not do**

- Do not give *Simvahexal* to anyone else, even if they have the same condition as you.
- Do not stop taking *Simvahexal* or lower the dosage without checking with your doctor.
- Do not take *Simvahexal* to treat any other complaint unless your doctor tells you to.

**Things to be careful of**

- *Simvahexal* is not known to influence ability to drive or operate machinery. However, it is advisable to know how this medicine affects you before driving or operating machinery as some patients may experience dizziness after taking simvastatin.

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## 6. POSSIBLE SIDE EFFECTS

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Like all medicines, *Simvahexal* can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- anaemia
- headache
- tingling sensation
- dizziness
- nerve pain/ numbness
- constipation
- abdominal pain
- flatulence
- indigestion
- diarrhea
- nausea
- vomiting
- inflammation of the pancreas
- hepatitis / jaundice
- skin rash, itchy, hair loss
- muscle pain / cramps

Inform your doctor immediately if you notice the following rare side effects:

- Swelling of the face, lips, tongue, throat, hands and feet
- lupus-like syndrome with symptoms such as skin rashes, joint pain, fatigue, and arthritis
- pain and stiffness in the shoulders and neck

- difficulty in swallowing
- inflammation of the blood vessels
- easily bruised or bleed
- joint pain
- arthritis
- rashes and hives
- sensitive to light
- fever
- flushing
- difficulty in breathing, shortness of breath
- feeling uncomfortable or sick
- increases in liver enzyme

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.

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## 7. HOW TO STORE *Simvahexal*

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**Storage**

Keep in original packaging. Store in a cool (below 25°C), dry place, away from direct heat, light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach of children.

**Disposal**

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines.

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## 8. PRODUCT DESCRIPTION

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**What *Simvahexal* looks like and contents of the pack.**

***Simvahexal 10 mg film-coated tablets:*** Pale pink coated, oval, scored, convex tablet coded SIM 10 on one side.

***Simvahexal 20 mg film-coated tablets:*** Orange coated, oval, scored, convex tablet coded SIM 20 on one side.

Each tablet can be divided into equal halves.

**Active ingredient:**

Each *Simvahexal 10 mg* and *Simvahexal 20 mg film-coated tablets* contains 10 mg and 20 mg simvastatin respectively.

**Other ingredients:**

Starch, pregelatinised, lactose monohydrate, microcrystalline cellulose, butylhydroxyanisole, ascorbic acid, citric acid monohydrate, magnesium stearate, hypromellose, talc, titanium dioxide, red ferric oxide, yellow ferric oxide.

***Packing:***

Blisters pack of 7 tablets: pack in 28, 49 and 98 film coated tablets per box.

Blisters pack of 10 tablets: pack in 10, 20, 30, 40, 50 and 100 tablets per box.

***Registration No:***

Simvahexal 10mg Film-coated Tablet:

MAL11100001A

Simvahexal 20mg Film-coated Tablet:

MAL11100002A

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**9. MARKETING AUTHORISATION  
HOLDER AND MANUFACTURER**

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***Manufactured by***

Salutas Pharma GmbH  
Otto-von-Guericke-Allee 1,  
39179 Barleben, Germany

***For***

Hexal AG  
Industriestraße 25,  
83607 Holzkirchen,  
Germany.

***Marketing Authorization Holder***

**IMEKS Pharma Sdn. Bhd.**

No. 1 & 2, Jalan 6/33B,  
MWE Commercial Park,  
52000 Kuala Lumpur, Malaysia

***Date of revision***

February 2012