

Applicant: Unimed Healthcare (Pty) Ltd

Product Name: UNISIM 10, UNISIM 20 & UNISIM 40

Dosage form and strength: Each film-coated tablet contains Simvastatin 10 mg
Each film-coated tablet contains Simvastatin 20 mg
Each film-coated tablet contains Simvastatin 40 mg

Patient Information Leaflet (PIL) for Medicines for Human Use

UNISIM (film-coated tablets)

SCHEDULING STATUS S4

UNISIM 10 (film-coated tablets)

UNISIM 20 (film-coated tablets)

UNISIM 40 (film-coated tablets)

Simvastatin

Contains sugar: UNISIM 10 lactose monohydrate 72,21 mg per tablet,

UNISIM 20 contains lactose monohydrate 144,42 mg per tablet,

UNISIM 40 contains lactose monohydrate 288,84 mg per tablet.

Read all of this leaflet carefully before you start taking UNISIM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **UNISIM** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **UNISIM** is and what it is used for
2. What you need to know before you take **UNISIM**

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3. How to take **UNISIM**
4. Possible side effects
5. How to store **UNISIM**
6. Contents of the pack and other information

1. What **UNISIM** is and what it is used for

UNISIM is used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, **UNISIM** raises levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking **UNISIM**. **UNISIM** belongs to the class of medicines called statins.

UNISIM 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 (heterozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood.

UNISIM is also used if you have:

- coronary heart disease (CHD) and high cholesterol levels not responding to diet.

2. What you need to know before you take **UNISIM**

Do not take UNISIM:

- if you are hypersensitive (allergic) to simvastatin or other statin or any of the other ingredients of **UNISIM**
- if you currently have liver problems
- if you have unexplained persistent elevation of serum transaminase (liver enzymes)

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- if you are pregnant or breastfeeding
- if you are taking one or more of the following medicines at the same time:
 - itraconazole, voriconazole, ketoconazole, or posaconazole (medicines for fungal infections)
 - erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
 - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
 - boceprevir, telaprevir (medicine used to treat hepatitis C)
 - nefazodone (a medicine for depression)
 - cobicistat (used to treat HIV infection)
 - gemfibrozil (a medicine for lowering cholesterol)
 - ciclosporin (a medicine often used in organ transplant patients)
 - danazol (a man-made hormone used to treat endometriosis: a female health disorder that occurs when cells from the lining of the womb (uterus) grow in other areas of the body)
 - lomitapide (used to lower familial cholesterol) with more than 40 mg of **UNISIM**.

Safety of **UNISIM** in porphyria (a group of rare blood pigment disorders) has not been established.

Warnings and precautions

Take special care with UNISIM:

- Tell your doctor if you drink large amounts of alcohol.
- Tell your doctor if you have ever had liver disease. **UNISIM** may not be right for you.

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- Tell your doctor if you develop kidney failure resulting from muscle breakdown (rhabdomyolysis). Other factors which can lead to kidney failure include severe infection, low blood pressure, severe problems with your metabolism (a process by which your body uses to get or make energy from the food you eat), problems with your hormonal system, imbalance of electrolyte (such as potassium, sodium), uncontrolled fits, operation or injury.
- Tell your doctor if you are due to have an operation. You may need to stop taking **UNISIM** for a short time.
- Your doctor should do a blood test before you start taking **UNISIM**. 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 **UNISIM**.
- While you are taking **UNISIM** 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.
- If you are using any other medicines such as immunosuppressants, fibrates (except fenofibrate), lipid lowering doses of niacin, amiodarone, amlodipine, verapamil, diltiazem or daptomycin (also see Do not take **UNISIM**).
- If you are Asian.
- 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 breakdown resulting in kidney damage and, rarely, death.

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You should stop UNISIM immediately, if you have been diagnosed with muscle problems (myopathy) or suspect that you have myopathy.

Your doctor may monitor creatine kinase (an enzyme marker for muscle problems) levels in your blood periodically especially when you are starting **UNISIM** therapy or your dose of **UNISIM** is increased.

The risk of muscle breakdown is greater at higher doses of **UNISIM**, particularly the 80 mg dose. The risk of muscle breakdown is also greater in certain patients. You might be more at risk to develop muscle problems and should speak with your doctor if any of the following applies:

- if you are older than 65 years,
- if you are a female,
- if you have kidney problems,
- if you have uncontrolled hypothyroidism,
- if you have a personal or family history of muscle disorders,
- if you have previously experienced muscle disorders with statin or fibrate use,
- if you consume large amounts of alcohol.

UNISIM may cause weakness and rapid fatigue of muscles under voluntary control (myasthenia gravis). The symptoms might only be limited to eye muscles (ocular myasthenia).

Children and adolescents

It is not recommended for children as the safety and efficacy has not been established.

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Other medicines with UNISIM

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

It is particularly important to tell your doctor if you are taking any of the following medicines.

Taking **UNISIM** with any of these medicines can increase the risk of muscle problems (some of these have already been listed in the above section “**Do not take UNISIM**”).

- ciclosporin (a medicine used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis)
- medicines with the active ingredient like itraconazole, ketoconazole, fluconazole, voriconazole or posaconazole (medicines for fungal infections)
- fibrates like gemfibrozil (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)
- nefazodone (a medicine for depression)
- medicines with the active ingredient cobicicstat (used to treat HIV infection)
- boceprevir, telaprevir, elbasvir or grazoprevir (medicine used to treat hepatitis C)
- oral fusidic acid (medicine used to treat a bacterial infection). If you need to take oral fusidic acid you will need to temporarily stop taking this medicine. Your doctor will tell you when it is safe to start **UNISIM** again. Taking **UNISIM** with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis)
- amiodarone (used to treat an irregular heartbeat)

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- verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- lomitapide (used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a medicine used to treat complicated skin infections and bacteraemia). It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin (e.g. **UNISIM**). Your doctor may decide that you stop treatment with **UNISIM** while taking daptomycin for a while
- ticagrelor (antiplatelet medicine)
- colchicine (used to treat gout).

Also, tell your doctor or pharmacist if you are taking or have recently taken any of the following:

- medicines to prevent blood clots, such as warfarin, (anticoagulants)
- cholestyramine (another medicine for lowering cholesterol)
- niacin (another medicine for lowering cholesterol)
- digoxin (a medicine for used to treat heart problems)
- rifampicin (used to treat tuberculosis).

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

You should also tell any doctor who is prescribing a new medicine for you that you are taking **UNISIM**.

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UNISIM with food and drink

Grapefruit juice contains one or more components that alter how the body uses some medicines, including **UNISIM**. Consuming grapefruit juice should be avoided.

Pregnancy and breastfeeding

You should not take **UNISIM** if you are pregnant or breastfeeding your baby.

Do not take **UNISIM** if you are pregnant, trying to get pregnant or think you may be pregnant.

If you get pregnant while taking **UNISIM**, stop taking it immediately and contact your doctor.

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

If you are pregnant or breastfeeding ~~your baby~~, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **UNISIM**.

Driving and using machines

UNISIM may cause dizziness. You should not drive or use machinery until you know what the effect of **UNISIM** will be on you. If you feel dizzy during treatment with **UNISIM**, consult your doctor before attempting to drive or use machines.

It is not always possible to predict to what extent **UNISIM** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **UNISIM** affects them.

UNISIM contains lactose monohydrate

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UNISIM contains lactose monohydrate. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **UNISIM**.

3. How to take **UNISIM**

Do not share medicines prescribed for you with any other person.

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

The usual starting dose of **UNISIM** is 10 mg to 20 mg taken once daily every evening. Your doctor may increase or decrease your daily dose at intervals of at least 4 weeks. The maximum recommended daily dose is 80 mg.

Your doctor will determine the appropriate tablet strength for you, depending on your condition.

Your doctor will tell you how long your treatment with **UNISIM** tablets will last.

If you have the impression that the effects of **UNISIM** is too strong or too weak, tell your doctor or pharmacist.

Children

UNISIM should not be given to children, since the safety and effectiveness of **UNISIM** have not been determined in children.

If you take more **UNISIM** than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the **UNISIM** pack with you.

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If you forget to take a UNISIM

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking UNISIM

- your cholesterol may rise again.

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

4. Possible side effects

UNISIM can have side effects.

Not all side effects reported for **UNISIM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **UNISIM**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **UNISIM** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- hypersensitivity (allergic) reactions including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing,
 - severe muscle pain usually in the shoulders and hips,
 - rash with weakness of limbs and neck muscles,
 - pain or inflammation of the joints,
 - inflammation of the blood vessels,

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- unusual bruising, 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).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **UNISIM**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the way your heart beats, for example, if you notice it beating irregular and often very fast,
- muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage,
- numbness or weakness of the arms and legs (peripheral neuropathy),
- inflammation of the pancreas, often with severe upper stomach pain, nausea and vomiting (pancreatitis),
- 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

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- feeling sick (nausea), being sick (vomiting), wind, indigestion, stomach pain,
- myalgia (soreness and achiness in the muscles that can range from mild to severe),
- muscle cramps.

Less frequent side effects:

- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (low number of red blood cells), frequent infections such as fever, severe chills, sore throat or mouth (low number of white blood cells),
- diabetes,
- trouble sleeping,
- headache, dizziness, tiredness, pins and needles (paraesthesia),
- poor memory, memory loss, confusion,
- photosensitivity, blurred vision, impaired vision,
- shortness of breath, hypersensitivity pneumonitis (inflamed lungs),
- constipation, diarrhoea,
- skin rash, itching, loss of hair (alopecia), urticaria (hives),
- lichenoid drug eruptions (violaceous, scaling papules and plaques that are typically symmetrical and widespread),
- muscle pain, muscle cramps, muscle inflammation, unusual weakness, muscle rupture,
- breast enlargement in men (gynaecomastia).

Frequency unknown:

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- weight gain,
- depression,
- sleep disturbances, including nightmares,
- weakness and rapid fatigue of muscles under voluntary control (myasthenia gravis).

The symptoms might only be limited to eye muscles (ocular myasthenia),

- interstitial lung disease,
- respiratory infections, bronchitis, sinusitis,
- immune-mediated necrotising myopathy (IMNM),
- erectile dysfunction,
- sexual dysfunction.

Effect on Laboratory tests

- low level blood cells (red, white and platelets),
- increased creatine kinase (from muscle) in blood,
- presence of myoglobin in urine (marker for muscle breakdown),
- increase in blood transaminase, alkaline phosphatase, gamma glutamyl transpeptidase (liver function enzymes),
- increase in blood glucose.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **UNISIM**.

5. How to store UNISIM

Store at or below 25 °C, protected from light and moisture. Do not remove the blisters from the carton until required for use.

Store all medicines out of reach of children.

Do not take **UNISIM** after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UNISIM contains:

The active substance in **UNISIM** is simvastatin.

UNISIM 10: Each tablet contains simvastatin (micronised) 10 mg.

Contains sugar: Lactose monohydrate 72,21 mg per tablet.

Also contains:

Butylated hydroxyanisole NMT 0,0389 % *m/m* (antioxidant)

Ascorbic acid NMT 2,676 % *m/m* (antioxidant synergist)

Citric acid monohydrate NMT 1,338 % *m/m* (sequesterant)

UNISIM 20: Each tablet contains simvastatin (micronised) 20 mg.

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Dosage form and strength: Each film-coated tablet contains Simvastatin 10 mg
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Contains sugar: Lactose monohydrate 144,42 mg per tablet.

Also contains:

Butylated hydroxyanisole NMT 0,0389 % m/m (antioxidant)

Ascorbic acid NMT 2,676 % m/m (antioxidant synergist)

Citric acid monohydrate NMT 1,33 8 % m/m (sequesterant)

UNISIM 40: Each tablet contains simvastatin (micronised) 40 mg.

Contains sugar: Lactose monohydrate 288,84 mg per tablet.

Also contains:

Butylated hydroxyanisole NMT 0,0389 % *m/m* (antioxidant)

Ascorbic acid NMT 2,676 % *m/m* (antioxidant synergist)

Citric acid monohydrate NMT 1,338 % *m/m* (sequesterant)

The other ingredients in **UNISIM** are:

Croscarmellose sodium, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, tablet coating consisting of hydroxypropyl cellulose (E463), hypromellose (E464), iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), talc (E553 b), titanium dioxide (E171).

What UNISIM looks like and contents of the pack

UNISIM 10: Peach coloured, film-coated, oval shaped tablets debossed with 'SST' on one side and '10' on other side with intact coating.

UNISIM 20: Tan coloured, film-coated, oval shaped tablets debossed with 'SST' on one side and '20' on other side with intact coating.

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Dosage form and strength: Each film-coated tablet contains Simvastatin 10 mg
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UNISIM 40: Brick red coloured, film-coated, oval shaped tablets debossed with 'SST' on one side and '40' on other side with intact coating.

Cartons containing 28, 30 or 100 tablets packed in PVdC coated PVC blister strips.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road & Bluegum Avenue

Anchorville

Lenasia, 1827

South Africa

This leaflet was last revised in

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