

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADCO SIMVASTATIN 10 mg, Tablets

ADCO SIMVASTATIN 20 mg, Tablets

ADCO SIMVASTATIN 40 mg, Tablets

Simvastatin

Contains sugar: Anhydrous lactose

ADCO SIMVASTATIN 10 mg contains 74,5 mg

ADCO SIMVASTATIN 20 mg contains 149 mg

ADCO SIMVASTATIN 40 mg contains 298 mg

Read all of this leaflet carefully before you start taking ADCO SIMVASTATIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- ADCO SIMVASTATIN 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 ADCO SIMVASTATIN is and what it is used for
2. What you need to know before you take ADCO SIMVASTATIN
3. How to take ADCO SIMVASTATIN
4. Possible side effects
5. How to store ADCO SIMVASTATIN
6. Contents of the pack and other information

1. What ADCO SIMVASTATIN is and what it is used for

ADCO SIMVASTATIN contains the active substance simvastatin. It belongs to the class of medicines called statins.

ADCO SIMVASTATIN is used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, ADCO SIMVASTATIN raise levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking ADCO SIMVASTATIN.

ADCO SIMVASTATIN 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)
- Heart disease and high cholesterol and not responding to change in diet to:
 - reduce the risk of death
 - reduce the risk of heart attack
 - reduce the risk of receiving surgery such as a bypass

- Slow the progression of heart disease

2. What you need to know before you take ADCO SIMVASTATIN

Do not take ADCO SIMVASTATIN

- if you are hypersensitive (allergic) to simvastatin or any of the other ingredients of ADCO SIMVASTATIN (listed in section 6)
- if you currently have liver problems
- if you have a disorder called porphyria
- if you are pregnant or breastfeeding
- unexplained raised levels of liver enzymes
- if you are taking medicine (s) with one or more than one of the following active ingredients:
 - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
 - erythromycin, clarithromycin or telithromycin (antibiotics for infections)
 - HIV protease inhibitors such as ritonavir, saquinavir, nelfinavir (HIV protease inhibitors are used for HIV infections)
 - boceprevir and telaprevir (medicines used to treat hepatitis C)
 - nefazodone (a medicine for depression)
 - medicines containing cobicistat
 - 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)
- if you have homozygous familial hypercholesterolaemia (HoFH), do not take lomitapide together with more than 40 mg of ADCO SIMVASTATIN. Taking these medicines together at higher doses may increase your risk of muscle problems or liver damage.

Warnings and precautions

Take special care with ADCO SIMVASTATIN

- if you drink large amounts of alcohol
- if you have ever had liver disease. ADCO SIMVASTATIN may not be right for you
- if you develop kidney failure resulting from muscle breakdown (rhabdomyolysis)
- if you are due to have an operation. You may need to stop taking ADCO SIMVASTATIN for a short time
- your doctor should do a blood test before you start taking ADCO SIMVASTATIN. 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 ADCO SIMVASTATIN tablets
- while you are taking ADCO SIMVASTATIN 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

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- if you have severe lung disease
- if you are Chinese, because a different dose may be applicable to you
- if you have a rare inherited condition that affects how your body processes certain sugars (such as galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption)
- if you have muscle weakness (including eye muscle weakness), this medicine may make it worse or cause it to start; stop taking it and contact your doctor if these symptoms occur

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

The risk of muscle diseases is greater at higher doses of ADCO SIMVASTATIN, 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:

- if you are older than 65 years
- if you are a female
- if you have kidney problems
- If you have uncontrolled low levels thyroid hormones (hypothyroidism)
- if you have a personal or family history of muscle disorders
- if you previously experienced muscle disorders with statin or fibrate use
- if you consume large amounts of alcohol

Children and adolescents

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

Other medicines and ADCO SIMVASTATIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) It is particularly important to tell your doctor if you are taking any of the following medicines. Taking ADCO SIMVASTATIN 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 ADCO SIMVASTATIN").

- ciclosporin (a medicines used inn organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- 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)

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- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS)
- nefazodone (a medicine for depression)
- boceprevir, telaprevir, elbasvir, grazoprevir (medicine used to treat hepatitis C)
- amiodarone (used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- colchicine (used to treat gout)
- medicines with the active ingredient cobicistat (used to treat HIV infection)
- lomitapide (used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a medicine used to treat complicated skin and skin structure 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. ADCO SIMVASTATIN). Your doctor may decide that you stop taking ADCO SIMVASTATIN for a while.
- ticagrelor (antiplatelet medicine)

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 used to treat heart problems)
- rifampicin (medicine 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 ADCO SIMVASTATIN.

ADCO SIMVASTATIN with food, drink and alcohol

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

Pregnancy, breastfeeding and fertility

Do not take ADCO SIMVASTATIN if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking ADCO SIMVASTATIN, stop taking it immediately and contact your doctor. Do not take ADCO SIMVASTATIN if you are breastfeeding, because it is not known if the medicine is passed into breast milk. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

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

ADCO SIMVASTATIN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take ADCO SIMVASTATIN

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

Always take ADCO SIMVASTATIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should stay on a cholesterol-lowering diet while taking ADCO SIMVASTATIN.

The usual initial dose is 10 mg or 20 mg/day given as a single dose in the 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 ADCO SIMVASTATIN will last.

If you have the impression that the effect of ADCO SIMVASTATIN is too strong or too weak, tell your doctor or pharmacist. If your doctor has prescribed ADCO SIMVASTATIN along with another medicine for lowering cholesterol containing any bile acid sequestrant, you should take ADCO SIMVASTATIN at least 1 hour before or 4 hours after taking the bile acid sequestrant.

If you take more ADCO SIMVASTATIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ADCO SIMVASTATIN

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 double dose to make up for forgotten individual doses.

If you stop taking ADCO SIMVASTATIN

Talk to your doctor or pharmacist because your cholesterol may rise again.

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

4. Possible side effects

ADCO SIMVASTATIN can have side effects.

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Not all side effects reported for ADCO SIMVASTATIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO SIMVASTATIN, please consult your health care provider for advice.

If any of the following happens, stop taking ADCO SIMVASTATIN and tell your doctor immediately or go to the casualty department 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 (angioedema).
 - Severe muscle pain usually in the shoulders and hips.
 - Rash with weakness of limbs and neck muscles.
 - Pain or inflammation of the joints (polymyalgia rheumatica).
 - Inflammation of the blood vessels (vasculitis).
 - Unusual bruising, skin eruptions and swelling (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing.
 - Shortness of breath (dyspnoea) and feeling unwell.
 - Lupus-like disease (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 reaction to ADCO SIMVASTATIN. 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:

- 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.
- Changes in the way your heart beats, for example, if you notice it beating irregular and often very fast.

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

Tell your doctor if you notice any of the following:

Less frequent

- Tiredness, headaches, being short of breath when exercising, dizziness and looking pale (low number of red blood cells), high number disease-fighting white blood cells, low number of platelets.
- Headache, dizziness, tiredness, pins and needles (paraesthesia).
- Poor memory, memory loss, confusion.
- Blurred vision; impaired vision.
- Constipation, diarrhoea, feeling sick (nausea), being sick (vomiting), wind, indigestion, stomach pain.

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- Skin rash, loss of hair (alopecia), itching, rash that may occur on the skin or sores in the mouth (lichenoid medicine eruptions).
- Muscle pain, muscle cramps, muscle inflammation, unusual weakness.
- Trouble sleeping.
- Diabetes, This is more likely if you have high levels of sugars and fats in your blood.
- Gynecomastia (breast enlargement in men).

Unknown frequency

- Weight gain.
- Sexual dysfunction.
- 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.
- Depression, sleep disturbances, including nightmares.
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).
- Lack of energy.

Effect on Laboratory tests

Elevations in some laboratory blood tests of liver function (blood transaminase, alkaline phosphatase, gamma glutamyl transpeptidase) and a muscle enzyme (creatine kinase) have been observed.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO SIMVASTATIN.

5. How to store ADCO SIMVASTATIN

- Store all medicines out of reach of children.
- Keep well closed. Keep blister in carton until required for use.
- Store in a dry place, at or below 25 °C in the original package.
- Do not take ADCO SIMVASTATIN 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 ADCO SIMVASTATIN contains:

The active substance is simvastatin (10 mg, 20 mg or 40 mg).

The other ingredients are lactose anhydrous, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch and butylhydroxyanisole. Tablet coating contains hydroxypropylcellulose, methylhydroxypropyl cellulose, talc, titanium dioxide (E171), iron oxide yellow (E172).

What ADCO SIMVASTATIN looks like and contents of the pack

ADCO SIMVASTATIN 10 mg tablets:

White, oblong, biconvex, film-coated tablets, scored on the one side. The tablets are debossed with "SVT" on the unscored side and "10" on the scored side.

ADCO SIMVASTATIN 20 mg tablets:

White, oblong, biconvex, film-coated tablets, scored on the one side. The tablets are debossed with "SVT" on the unscored side and "20" on the scored side.

ADCO SIMVASTATIN 40 mg tablets:

White, oblong, biconvex, film-coated tablets, scored on the one side. The tablets are debossed with "SVT" on the unscored side and "40" on the scored side.

ADCO SIMVASTATIN 10 mg, 20 mg & 40 mg tablets:

Blister packaging:

The tablets are packed in PVC/PE/PVDC: Al blisters (Primary packaging material). Depending on the pack size one or more blisters are packed into a carton box (Secondary packaging).

The white blister packs of PVC/PE/PVDC/Al and the blister packs of PVC/PE/PVDC/Al in Al sachets, are both available as cartons of 10, 20, 30, 50 or 100 tablets, where the tablets are enclosed in blister strips of 10 tablets or 15 tablets each. The white blister packs of PVC/PE/PVDC/Al and the blister packs of PVC/PE/PVDC/Al in Al sachets, are also available as cartons of 14 or 28 tablets, where the tablets are enclosed in blister strips of 14 tablets each.

Container packaging:

A prescribed number of tablets is packed in an HDPE container (Primary packaging material).

Each container is sealed with an aluminium seal and closed with a polypropylene closure.

The 300 ml white HDPE tablet containers with child resistant polypropylene closures contain 100 or 300 tablets.

Not all pack sizes will be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

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Midrand 1685.

Customer Care: 0860 ADCOCK / 232625

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Registration number(s)

ADCO SIMVASTATIN 10 mg: 35/7.5/0277

ADCO SIMVASTATIN 20 mg: 35/7.5/0278

ADCO SIMVASTATIN 40 mg: 35/7.5/0279

Botswana		
	Product name	Registration number
Schedule 2	Adco-Simvastatin 10 mg	BOT1001740A/B/C/D/E/F/G
Schedule 2	Adco-Simvastatin 20 mg	BOT1001741A/B/C/D/E/F/G
Schedule 2	Adco-Simvastatin 40 mg	BOT0801458
Namibia		
NS2	Adco-Simvastatin 10 mg	05/7.5/0130
NS2	Adco-Simvastatin 20 mg	05/7.5/0131
NS2	Adco-Simvastatin 40 mg	05/7.5/0132

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