

APO-EZETIMIBE/ SIMVASTATIN

Ezetimibe/Simvastatin

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about APO-Ezetimibe/Simvastatin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking APO-Ezetimibe/Simvastatin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

APO-Ezetimibe/Simvastatin helps to lower cholesterol and triglyceride levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately is used to treat high cholesterol.

Cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called 'good' cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How APO-Ezetimibe/Simvastatin works

APO-Ezetimibe/Simvastatin reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.

APO-Ezetimibe/Simvastatin works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver. APO-Ezetimibe/Simvastatin does not help you lose weight.

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), APO-Ezetimibe/

Simvastatin reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

APO-Ezetimibe/Simvastatin is not addictive.

This medicine is available only with a doctor's prescription.

Use in Children and Adolescents

APO-Ezetimibe/Simvastatin is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e. passed on through families).

APO-Ezetimibe/Simvastatin is not recommended for use in children under 10 years of age, as there have been no studies of its effects in this age group.

Your doctor will assess whether APO-Ezetimibe/Simvastatin is suitable for your child. Depending on the pubertal development of your child, APO-Ezetimibe/Simvastatin may not be suitable for him or her.

Before you take this medicine

When you must not take it

Do not take APO- Ezetimibe/ Simvastatin if you have an allergy to:

- ezetimibe
- simvastatin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if:

- you have active liver disease or repeated blood tests indicating possible liver problems.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you are taking certain medicines such as gemfibrozil, cyclosporin, danazol, fusidic acid and strong CYP3A4 inhibitors like itraconazole and ketoconazole. Please see the section "Taking other medicines" in this CMI for more information.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy, causing foetal malformations (birth defects) or irreversible damage.

Do not breastfeed if you are taking this medicine.

The active ingredient in this medicine passes into breast milk (if applicable) and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if:

- you 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.
- you are Asian.
- you are taking niacin or a niacin-containing product.
- you have, or have had, any medical conditions, including liver disease or liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.
- you have kidney disease, diabetes or any other medical problems.
- you drink alcohol regularly.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with APO-Ezetimibe/Simvastatin.

These include:

- nefazodone, used to treat depression
- medicines containing cobicistat, a drug used in the treatment of HIV infection
- protease inhibitors used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- certain protease inhibitors used to treat Hepatitis C virus infection, such as boceprevir or telaprevir
- gemfibrozil, used to treat high cholesterol levels
- cyclosporin, used to suppress the immune system
- danazol
- erythromycin, clarithromycin, telithromycin and fusidic acid, antibiotics used to treat infections
- ketoconazole, itraconazole, posaconazole and voriconazole, used to treat certain fungal infections

If you are taking any of the above, your doctor may suggest stopping APO-Ezetimibe/Simvastatin temporarily or permanently.

Some medicines and APO-Ezetimibe/Simvastatin may interfere with each other. These include:

- bile acid sequestrants, such as cholestyramine, used to lower cholesterol levels
- other medicines to lower cholesterol levels, for example, other fibrates, nicotinic acid (also known as niacin)
- warfarin, fludione, or other drugs used to prevent blood clots
- colchicine, used for gout
- verapamil, used to treat high blood pressure and angina
- diltiazem, used to treat angina
- amiodarone, used to treat irregular heart beat
- amlodipine, used to treat high blood pressure and angina
- digoxin, used to treat heart failure

- Iomitapide (a drug used to treat a serious and rare genetic cholesterol condition)

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take APO-Ezetimibe/Simvastatin only when prescribed by your doctor.

The recommended dose in adults (18 years and over) is one APO-Ezetimibe/Simvastatin 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening. Your doctor will adjust your APO-Ezetimibe/Simvastatin dose depending on your response.

The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one APO-Ezetimibe/Simvastatin 10/10, 10/20 or 10/40 tablet once a day, in the evening. The maximum recommended dose in adolescents is 10/40 mg.

Because of the increased risk of muscle problems, the APO-Ezetimibe/Simvastatin 10/80 tablet is only for patients at high risk of heart disease problems who have not yet reached their cholesterol goal on lower doses.

How to take it

Swallow APO-Ezetimibe/Simvastatin tablets whole with a full glass of water.

When to take it

APO-Ezetimibe/Simvastatin should 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, APO-Ezetimibe/Simvastatin 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.

However, take APO-Ezetimibe/Simvastatin about the same time each day.

Taking APO-Ezetimibe/Simvastatin at the same time each day will have the best effect. It will also help you remember when to take your dose.

Your doctor may ask you to take APO-Ezetimibe/Simvastatin with other cholesterol lowering agents such as bile acid sequestrants.

If you are taking a bile acid sequestrant, such as cholestyramine, take your APO-Ezetimibe/Simvastatin either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take it

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

APO-Ezetimibe/Simvastatin helps lower your cholesterol. It does not cure your condition.

Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down.

You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking APO-Ezetimibe/Simvastatin, your cholesterol levels may rise again.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

While you are using this medicine

Things you must do

If you become pregnant while taking APO-Ezetimibe/Simvastatin, stop taking it and tell your doctor immediately.

Have your blood fats checked when your doctor says, to make sure APO-Ezetimibe/Simvastatin is working.

Even if you are taking medicines to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking APO-Ezetimibe/Simvastatin.

If you are about to have elective surgery, tell your doctor that you are taking APO- Ezetimibe/ Simvastatin.

Your doctor may suggest stopping the tablets a few days before surgery.

Things you must not do

Do not give APO- Ezetimibe/ Simvastatin to anyone else, even if they have the same condition as you.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of APO- Ezetimibe/Simvastatin causing liver problems.

Grapefruit juice should be avoided while taking APO- Ezetimibe/ Simvastatin.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including APO- Ezetimibe/ Simvastatin.

Be careful driving or operating machinery until you know how APO-Ezetimibe/Simvastatin affects you.

There have been side effects reported with APO-Ezetimibe/Simvastatin that may affect your ability to drive or operate machinery.

Individual responses to APO-Ezetimibe/Simvastatin may vary.

High cholesterol can be treated in two main ways:

Lifestyle Changes

This includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for advice before increasing physical activity.

Medicines

Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-Ezetimibe/Simvastatin.

APO-Ezetimibe/Simvastatin helps most people with high cholesterol, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to accident and emergency at your nearest hospital, if you notice any of the following:

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

These are serious side effects. If you have them, you may have had a serious allergic reaction to APO-Ezetimibe/Simvastatin. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor immediately if you notice any of the following:

- skin rash and hives
- raised red rash, sometimes with target-shaped lesions
- dark coloured urine
- light coloured bowel motions
- joint pain
- bleeding or bruising more easily than normal
- steady abdominal pain with nausea and vomiting.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Liver problems can also occur and may be serious. Your doctor may do blood tests to check your liver

Tell your doctor immediately if you notice any of the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of the skin or the white of your eyes.

Tell your doctor immediately if you notice the following:

- unexplained muscle aches, tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping APO- Ezetimibe/ Simvastatin).

This may be a serious side effect. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. You may need urgent medical attention.

The risk of muscle breakdown is greater at higher doses of APO-Ezetimibe/Simvastatin, particularly the 10/80 mg dose.

The risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Tell your doctor if you notice any of the following:

- Headache
- Nausea
- Muscle aches
- Dizziness
- Feeling tired
- Cough
- Stomach irritation

- Diarrhoea
- Decreased appetite
- Weight decreased
- Indigestion
- Flatulence
- Abdominal bloating
- Dry mouth
- Heart burn
- Constipation
- Hot flush
- Hypertension
- Pain

These are the more common side effects of APO- Ezetimibe/ Simvastatin or of either ezetimibe or simvastatin.

Tell your doctor if you notice any of the following:

- Depression
- Tingling or numbness of the hands or feet
- Trouble sleeping
- Poor memory
- Confusion
- Erectile dysfunction
- Breathing problems including persistent cough and/or shortness of breath, that may also occur with fatigue, unexplained weight loss or fever

These are rare side effects of ezetimibe or simvastatin.

In adolescent patients (10 to 17 years of age) there have been no studies longer than 1 year of the effect of taking APO-Ezetimibe/ Simvastatin on bone development, growth, social and emotional development, or fertility.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Storage and Presentation

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep APO-Ezetimibe/Simvastatin in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking APO-Ezetimibe/Simvastatin or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

APO-Ezetimibe/Simvastatin comes in four types of tablets:

- APO-Ezetimibe/Simvastatin 10/10 - 10mg Ezetimibe/10mg Simvastatin: Light tan, mottled, round, biconvex, 6mm tablets with markings "511" on one side - AUST R 279116.
- APO-Ezetimibe/Simvastatin 10/20 - 10mg Ezetimibe/ 20mg Simvastatin: Light tab, mottled, round, biconvex, 8mm tablets with markings "512" on one side - AUST R 279099.
- APO-Ezetimibe/Simvastatin 10/40 - 10mg Ezetimibe/ 40mg

Simvastatin: Light tan, mottled, round, biconvex, 10mm tablets with markings "513" on one side - AUST R 279121.

- APO-Ezetimibe/Simvastatin 10/80 - 10mg Ezetimibe/ 80mg Simvastatin: Light tab, mottled, capsule shaped, biconvex, 17.5 x 7.55mm tablets with markings "515" on one side - AUST R 279123.

A starter blister pack of APO-Ezetimibe/Simvastatin contains 5 or 10 tablets. A trade blister pack contains 30 tablets.

Ingredients

Active ingredient:

APO-Ezetimibe/Simvastatin 10/10
-

10mg ezetimibe/10mg simvastatin per tablet

APO-Ezetimibe/Simvastatin 10/20
-

10mg ezetimibe/20mg simvastatin per tablet

APO-Ezetimibe/Simvastatin 10/40
-

10mg ezetimibe/ 40mg simvastatin per tablet

APO-Ezetimibe/Simvastatin 10/80
-

10mg ezetimibe/ 80mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- citric acid
- croscarmellose sodium
- hypromellose
- lactose monohydrate
- ascorbic acid
- magnesium stearate
- microcrystalline cellulose
- propyl gallate
- iron oxide yellow (E172)
- iron oxide red (E172)
- iron oxide black (E172)

APO-Ezetimibe/Simvastatin does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Medis Pharma Pty Limited
1002/53 Walker Street,
North Sydney, NSW, 2060
Australia

Distributor

This medicine is distributed in Australia by:

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

This leaflet was prepared in June 2018.