

APO-EZETIMIBE/SIMVASTATIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-EZETIMIBE/SIMVASTATIN?

APO-EZETIMIBE/SIMVASTATIN contains the active ingredients ezetimibe and simvastatin. APO-EZETIMIBE/SIMVASTATIN is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

For more information, see Section [1. Why am I using APO-EZETIMIBE/SIMVASTATIN?](#) in the full CMI.

2. What should I know before I use APO-EZETIMIBE/SIMVASTATIN?

Do not use if you have ever had an allergic reaction to ezetimibe and simvastatin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-EZETIMIBE/SIMVASTATIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-EZETIMIBE/SIMVASTATIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-EZETIMIBE/SIMVASTATIN?

- The recommended dose is one APO-EZETIMIBE/SIMVASTATIN 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening.
- For the best effect take APO-EZETIMIBE/SIMVASTATIN at about the same time each day.

More instructions can be found in Section [4. How do I use APO-EZETIMIBE/SIMVASTATIN?](#) in the full CMI.

5. What should I know while using APO-EZETIMIBE/SIMVASTATIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-EZETIMIBE/SIMVASTATIN.• If you become pregnant while taking APO-EZETIMIBE/SIMVASTATIN, tell your doctor.• Have any blood tests your doctor requests to make sure APO-EZETIMIBE/SIMVASTATIN is right for you.
Things you should not do	<ul style="list-style-type: none">• Do not give APO-EZETIMIBE/SIMVASTATIN to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how APO-EZETIMIBE/SIMVASTATIN affects you.
Drinking alcohol	<ul style="list-style-type: none">• Drinking large quantities of alcohol while taking APO-EZETIMIBE/SIMVASTATIN may increase your chance of getting liver problems.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-EZETIMIBE/SIMVASTATIN in a cool dry place where the temperature stays below 25°C

For more information, see Section [5. What should I know while using APO-EZETIMIBE/SIMVASTATIN?](#) in the full CMI.

6. Are there any side effects?

Common side effects of APO-EZETIMIBE/SIMVASTATIN are diarrhoea and muscle pain.

Allergic reactions to ezetimibe, simvastatin or other ingredients of APO-EZETIMIBE/SIMVASTATIN occur very rarely. Serious side effects are rare, but may need urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-EZETIMIBE/SIMVASTATIN

Active ingredient(s): ezetimibe and simvastatin

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-EZETIMIBE/SIMVASTATIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-EZETIMIBE/SIMVASTATIN.**

Where to find information in this leaflet:

- [1. Why am I using APO-EZETIMIBE/SIMVASTATIN?](#)
- [2. What should I know before I use APO-EZETIMIBE/SIMVASTATIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-EZETIMIBE/SIMVASTATIN?](#)
- [5. What should I know while using APO-EZETIMIBE/SIMVASTATIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-EZETIMIBE/SIMVASTATIN?

APO-EZETIMIBE/SIMVASTATIN contains the active ingredients ezetimibe and simvastatin. APO-EZETIMIBE/SIMVASTATIN

APO-EZETIMIBE/SIMVASTATIN helps to lower cholesterol and triglyceride levels.

APO-EZETIMIBE/SIMVASTATIN is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

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.

Your doctor may have prescribed APO-EZETIMIBE/SIMVASTATIN for another reason. Ask your doctor if you have any questions about why APO-EZETIMIBE/SIMVASTATIN has been prescribed for you. APO-EZETIMIBE/SIMVASTATIN is not addictive.

2. What should I know before I use APO-EZETIMIBE/SIMVASTATIN?

Warnings

Do not use APO-EZETIMIBE/SIMVASTATIN if:

- you are allergic to ezetimibe and simvastatin, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat.
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breast feeding. APO-EZETIMIBE/SIMVASTATIN is contraindicated (i.e. should not be used) during pregnancy and breastfeeding. If you take this medicine during pregnancy and breastfeeding, your baby may absorb this medicine and it may affect your baby's normal development causing foetal malformations (birth defects) or irreversible damage.
- 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, ciclosporin, danazol, fusidic acid and strong CYP3A4 inhibitors like itraconazole and ketoconazole. Please see the [Section 3. What if I am Taking other medicines](#) in this CMI for more information.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have kidney disease, diabetes or any other medical condition.
- 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 Asian.
- 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.
- drink alcohol regularly.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- have or have had myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.
- are taking niacin or a niacin-containing product.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. APO-EZETIMIBE/SIMVASTATIN should not be used during pregnancy.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. APO-EZETIMIBE/SIMVASTATIN should not be used while breast feeding.

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.

3. What if I am taking other medicines?

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

Some medicines should not be taken with APO-EZETIMIBE/SIMVASTATIN. If you are taking any of them, your doctor may suggest stopping APO-EZETIMIBE/SIMVASTATIN temporarily or permanently. These include:

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

Some medicines and APO-EZETIMIBE/SIMVASTATIN may interfere with each other. These medicines may be affected by APO-EZETIMIBE/SIMVASTATIN, may affect how well it works, or may increase the risk of side effects with APO-EZETIMIBE/SIMVASTATIN. You may need different amounts of your medicine, or you may need to take different medicines or take your medicines at different times. These include:

- certain hepatitis c antiviral agents, such as elbasvir, or grazoprevir
- bile acid sequestrants, such as colestyramine, used to lower cholesterol levels.
- other medicines to lower cholesterol levels, for example, other fibrates, nicotinic acid (also known as niacin).
- warfarin, fluindione, ticagrelor 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
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking APO-EZETIMIBE/SIMVASTATIN.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-EZETIMIBE/SIMVASTATIN.

4. How do I use APO-EZETIMIBE/SIMVASTATIN?

How much to take

- 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.
- Swallow APO-EZETIMIBE/SIMVASTATIN with a glass of water.
- Follow the instructions provided and use APO-EZETIMIBE/SIMVASTATIN until your doctor tells you to stop

When to take APO-EZETIMIBE/SIMVASTATIN

- 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.
- Take APO-EZETIMIBE/SIMVASTATIN about the same time each day. A good time would be after your evening meal. However, it does not matter whether you take it before or after food
- 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 colestyramine, take your APO-EZETIMIBE/SIMVASTATIN either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take APO-EZETIMIBE/SIMVASTATIN

- 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 use APO-EZETIMIBE/SIMVASTATIN

APO-EZETIMIBE/SIMVASTATIN should be used regularly at the same time each day.

If it is almost time for 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 tablet as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take your tablet, ask your pharmacist for some hints.

If you use too much APO-EZETIMIBE/SIMVASTATIN

If you think that you have used too much APO-EZETIMIBE/SIMVASTATIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-EZETIMIBE/SIMVASTATIN?

Things you should do

Call your doctor straight away and stop taking APO-EZETIMIBE/SIMVASTATIN if you become pregnant while you are taking APO-EZETIMIBE/SIMVASTATIN.

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.

Remind any doctor, dentist or pharmacist you visit that you are using 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 should 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

- 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.

Things that may help your condition

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Avoid drinking large quantities of alcohol.

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

Looking after your medicine

- Keep APO-EZETIMIBE/SIMVASTATIN in a cool dry place where the temperature stays below 25°C.
- 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.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. If you take this medicine after the expiry date has passed, it may not work.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Muscle/skeleton related:</p> <ul style="list-style-type: none">• Muscle aches <p>Gastrointestinal-related:</p> <ul style="list-style-type: none">• Nausea• Stomach irritation• Diarrhoea <p>Heart and circulation-related:</p> <ul style="list-style-type: none">• Hypertension• Hot flush <p>Metabolism and nutrition-related:</p> <ul style="list-style-type: none">• Decreased appetite <p>Head and nervous system-related:</p> <ul style="list-style-type: none">• Headache• Dizziness <p>Respiratory-related:</p> <p>Cough</p> <p>General conditions:</p> <ul style="list-style-type: none">• Feeling tired• Pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are the more common side effects of APO-EZETIMIBE/SIMVASTATIN or of either ezetimibe or simvastatin.</p>
<p>Mood-related:</p> <ul style="list-style-type: none">• Depression• Trouble sleeping. <p>Head and nervous system-related:</p> <ul style="list-style-type: none">• Tingling or numbness of the hands or feet.• Poor memory.• Confusion. <p>Eye-related:</p> <ul style="list-style-type: none">• Blurred or impaired vision <p>Reproductive system or breast related:</p> <ul style="list-style-type: none">• Erectile dysfunction• Gynaecomastia (breast enlargement in men). (very rare) <p>Respiratory-related:</p> <ul style="list-style-type: none">• Breathing problems including persistent cough and/or shortness of	<p>Tell your doctor if you notice any of these.</p> <p>These are rare side effects of ezetimibe or simvastatin.</p>

Less serious side effects	What to do
<p>breath, that may also occur with fatigue, unexplained weight loss or fever.</p> <p>Muscle/skeleton related:</p> <ul style="list-style-type: none"> Muscle rupture (very rare) <p>Skin-related:</p> <ul style="list-style-type: none"> Rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions). (very rare) 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<ul style="list-style-type: none"> skin rash and hives severe skin problems dark coloured urine light coloured bowel motions joint pain bleeding or bruising more easily than normal steady abdominal pain with nausea and vomiting. 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 (symptoms of myasthenia). <p>Liver problems can also occur and may be serious. Your doctor may do blood tests to check your liver. Symptoms may include:</p> <ul style="list-style-type: none"> feel tired or weak loss of appetite upper belly pain dark urine yellowing of the skin or the white of your eyes. <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney</p>	<p>Tell your doctor immediately if you notice any of these side effects.</p> <p>These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.</p>

Serious side effects	What to do
<p>damage that can lead to death. Symptoms may include:</p> <ul style="list-style-type: none"> unexplained muscle aches, tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping APO-EZETIMIBE/SIMVASTATIN). <p>The risk of muscle breakdown is greater at higher doses of APO-EZETIMIBE/SIMVASTATIN, particularly the 10/80 mg dose and is greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-EZETIMIBE/SIMVASTATIN contains

Active ingredient (main ingredient)	Ezetimibe Simvastatin
Other ingredients (inactive ingredients)	Butylated hydroxyanisole Citric acid monohydrate Croscarmellose sodium Hypromellose Lactose monohydrate Magnesium stearate Microcrystalline cellulose Propyl gallate Ascorbic acid Ferric oxide red

Potential allergens	Lactose monohydrate
----------------------------	---------------------

Do not take this medicine if you are allergic to any of these ingredients.

What APO-EZETIMIBE/SIMVASTATIN looks like

- APO-EZETIMIBE/SIMVASTATIN 10/10 -:

Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '335' on one side and plain on other side. (AUST R 309732)

- APO-EZETIMIBE/SIMVASTATIN 10/20-:

Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '336' on one side and plain on other side. (AUST R 309770)

- APO-EZETIMIBE/SIMVASTATIN 10/40 -:

Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '337' on one side and plain on other side. (AUST R 309756)

APO-EZETIMIBE/SIMVASTATIN 10/80 -:

Light pink to pink colored with mosaic appearance, capsule shaped biconvex uncoated tablets '338' on one side and plain on other side. (AUST R 309758)

Available in Alu-Alu Blister packs of 5, 10 and 30

HDPE Bottle packs of 30

HDPE Bottle packs of 90, 500, 1000 (for dispensing use only).

Who distributes APO-EZETIMIBE/SIMVASTATIN

- Sponsor

Torrent Australasia Pty Ltd

Coleman & Greig L9/10 George St PARRAMATTA
WESTFIELD NSW 2150

This leaflet was prepared in November 2024.