

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 EzSimva GH?

EzSimva GH contains the active ingredients ezetimibe and simvastatin. EzSimva GH is used to help 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.

For more information, see Section [1. Why am I using EzSimva GH?](#) in the full CMI.

2. What should I know before I use EzSimva GH?

Do not use if you have ever had an allergic reaction to ezetimibe, 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 EzSimva GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EzSimva GH 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 EzSimva GH?

- The recommended dose in adults (18 years and over) is one tablet of the prescribed strength once a day, in the evening.
- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one tablet of the prescribed strength once a day, in the evening. The maximum recommended dose in adolescents is 10 mg/40 mg.

More instructions can be found in Section [4. How do I use EzSimva GH?](#) in the full CMI.

5. What should I know while using EzSimva GH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using EzSimva GH.• Have your blood fats checked when your doctor says to make sure EzSimva GH is working. If you are about to have elective surgery, tell your doctor that you are taking EzSimva GH• If you become pregnant while taking EzSimva GH, stop taking it and tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Grapefruit juice should be avoided while taking EzSimva GH.• Do not give EzSimva GH to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how EzSimva GH affects you.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking large quantities of alcohol. Drinking large quantities of alcohol may increase your chance of EzSimva GH causing liver problems.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using EzSimva GH?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common side effects are headache, nausea, muscle aches, dizziness, feeling tired, cough, stomach irritation, diarrhoea, decreased appetite, hot flush, hypertension, and pain.

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.

EzSimva GH

Active ingredient(s): ezetimibe and simvastatin

Consumer Medicine Information (CMI)

This leaflet provides important information about using EzSimva GH. **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 EzSimva GH.**

Where to find information in this leaflet:

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

1. Why am I using EzSimva GH?

EzSimva GH contains the active ingredients ezetimibe and simvastatin. EzSimva GH is a lipid modifying agent.

EzSimva GH is used to help 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.

EzSimva GH reduces elevated total- cholesterol, LDL (bad) cholesterol and triglycerides, and increases HDL (good) cholesterol.

EzSimva GH works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver.

EzSimva GH does not help you lose weight. If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), EzSimva GH reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Your doctor may have prescribed EzSimva GH for another reason. Ask your doctor if you have any questions about why EzSimva GH has been prescribed for you.

EzSimva GH is not addictive.

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.

2. What should I know before I use EzSimva GH?

Warnings

Do not use EzSimva GH if:

- you are allergic to ezetimibe, simvastatin or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have active liver disease or repeated blood tests indicating possible liver problems.
- 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.
- you are taking certain medicines such as gemfibrozil, ciclosporin, danazol, fusidic acid or 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.
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

Check with 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.
- are Asian.
- are taking niacin or a niacin-containing product.
- 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.
- have kidney disease, diabetes or any other medical problems.
- drink alcohol regularly.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- 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?](#)

Use in children and adolescents

EzSimva GH is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (ie. passed on through families). EzSimva GH 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 EzSimva GH is suitable for your child. Depending on the pubertal development of your child, EzSimva GH may not be suitable for them.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

EzSimva GH is contraindicated (ie. 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.

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 may interfere with EzSimva GH and affect how it works.

Some medicines should not be taken with EzSimva GH. 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;
- antibiotics used to treat infections, such as erythromycin, clarithromycin, telithromycin and fusidic acid;
- medicines used to treat certain fungal infections, such as ketoconazole, itraconazole, posaconazole and voriconazole.

If you are taking any of the above, your doctor may suggest stopping EzSimva GH temporarily or permanently.

Some medicines and EzSimva GH may interfere with each other. These include:

- certain hepatitis C antiviral agents, such as elbasvir, or grazoprevir;
- 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, fluindione, 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EzSimva GH.

4. How do I use EzSimva GH?

How much to take

- The recommended dose in adults (18 years and over) is one of the prescribed strength of tablet once a day, in the evening. Your doctor will adjust your EzSimva GH dose depending on your response.
- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one of the prescribed strength of tablet once a day, in the evening. The maximum recommended dose in adolescents is 10 mg/40 mg.
- Because of the increased risk of muscle problems, EzSimva GH 10/80 (10 mg/80 mg) is only for patients at high risk of heart disease problems who have not yet reached their cholesterol goal on lower doses.
- Follow the instructions provided and use EzSimva GH until your doctor tells you to stop

When to take EzSimva GH

- EzSimva GH 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, EzSimva GH 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.
- Take EzSimva GH about the same time each day. Taking EzSimva GH 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 EzSimva GH with other cholesterol lowering agents such as bile acid sequestrants.
If you are taking a bile acid sequestrant, such as cholestyramine, take your EzSimva GH either at least two hours before or four hours after taking the bile acid sequestrant.

How to take EzSimva GH

- Swallow EzSimva GH with a glass of water.

How long to take EzSimva GH

- EzSimva GH 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 EzSimva GH, your cholesterol levels may rise again.

If you forget to use EzSimva GH

EzSimva GH should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet 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.

If you use too much EzSimva GH

If you think that you have used too much EzSimva GH, 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 EzSimva GH?

Things you should do

If you become pregnant while taking EzSimva GH, stop taking it and tell your doctor immediately.

Have your blood fats checked when your doctor says, to make sure EzSimva GH 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 EzSimva GH.

If you are about to have elective surgery, tell your doctor that you are taking EzSimva GH.

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

Remind any doctor, dentist or pharmacist you visit that you are using EzSimva GH.

Things you should not do

- Do not give EzSimva GH to anyone else, even if they have the same condition as you.
- Avoid grapefruit juice while taking EzSimva GH. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including EzSimva GH.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EzSimva GH affects you.

There have been side effects reported with EzSimva GH that may affect your ability to drive or operate machinery. Individual responses to EzSimva GH may vary.

Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of EzSimva GH causing liver problems.

Looking after your medicine

- Keep EzSimva GH 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.

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
<ul style="list-style-type: none"> Headache. Nausea. 	Speak to your doctor if you

<ul style="list-style-type: none"> • Muscle aches. • Dizziness. • Feeling tired. • Cough. • Stomach irritation. • Diarrhoea. • Decreased appetite. • Hot flush. • Hypertension. • Pain. 	have any of these less serious side effects and they worry you.
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<ul style="list-style-type: none"> • Gynaecomastia (breast enlargement in men). • Muscle rupture. • Rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions). 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing. • 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. • Symptoms of liver problems: <ul style="list-style-type: none"> ○ feeling tired or weak; ○ loss of appetite; ○ upper belly pain; ○ yellowing of the skin or the white of your eyes. • Unexplained muscle aches, tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping EzSimva GH). 	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.

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 EzSimva GH 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 EzSimva GH looks like

EzSimva GH 10/10 is a light pink to pink coloured, with a mosaic appearance, capsule-shaped, biconvex, uncoated tablet marked with '335' on one side and plain on other side (AUST R 309744).

EzSimva GH 10/20 is a light pink to pink coloured, with a mosaic appearance, capsule-shaped, biconvex, uncoated

Rare side effects

Rare side effects	What to do
<ul style="list-style-type: none"> • Depression. • Tingling or numbness of the hands or feet. • Trouble sleeping. • Poor memory. • Confusion. • Blurred or impaired vision. • Erectile dysfunction. • Breathing problems including persistent cough and/or shortness of breath, that may also occur with fatigue. • Unexplained weight loss or fever. 	Call your doctor straight away if you notice any of these. These are rare side effects of ezetimibe or simvastatin.

tablet marked with '336' on one side and plain on other side (AUST R 309720).

EzSimva GH 10/40 is a light pink to pink coloured, with a mosaic appearance, capsule-shaped, biconvex, uncoated tablet marked with '337' on one side and plain on other side (AUST R 309738).

EzSimva GH 10/80 is a light pink to pink coloured, with a mosaic appearance, capsule-shaped, biconvex, uncoated tablet marked with '338' on one side and plain on other side (AUST R 309765).

Who distributes EzSimva GH

Generic Health Pty Ltd

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