EZETIMIBE VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking EZETIMIBE VIATRIS, speak to your doctor or pharmacist.

1. Why am I taking EZETIMIBE VIATRIS?

EZETIMIBE VIATRIS contains the active ingredient ezetimibe. EZETIMIBE VIATRIS is used to lower high cholesterol levels.

For more information, see Section 1. Why am I taking EZETIMIBE VIATRIS? in the full CMI.

2. What should I know before I take EZETIMIBE VIATRIS?

Do not use if you have ever had an allergic reaction to ezetimibe 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, are pregnant or breastfeeding or plan to become pregnant or breastfeed.

For more information, see Section 2. What should I know before I take EZETIMIBE VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EZETIMIBE VIATRIS 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 take EZETIMIBE VIATRIS?

- The recommended dose is 10 mg once a day.
- EZETIMIBE VIATRIS should be taken at about the same time each day.

More instructions can be found in Section 4. How do I take EZETIMIBE VIATRIS? in the full CMI.

5. What should I know while taking EZETIMIBE VIATRIS?

Things you must do	• Tell your doctor, dentist or pharmacist you visit that you are taking EZETIMIBE VIATRIS. • Have your blood cholesterol and triglycerides checked when your doctor says so to make sure EZETIMIBE VIATRIS is working. • Call your doctor straight away if you become pregnant while taking EZETIMIBE VIATRIS.
Things you must not do	• Do not stop taking EZETIMIBE VIATRIS suddenly • Do not increase or adjust the dose yourself
Driving or using machines	• Side effects have been reported that may affect your ability to drive or operate machinery. Be careful driving a car or operating machinery until you know if EZETIMIBE VIATRIS affects you.
Looking after your medicine	• Keep it in a cool dry place where the temperature stays below 25˚C.

For more information, see Section 5. What should I know while taking EZETIMIBE VIATRIS? in the full CMI.

6. Are there any side effects?

When EZETIMIBE VIATRIS is used as the only cholesterol lowering medicine, common side effects are abdominal pain, diarrhea, flatulence and fatigue.

Allergic reactions to ezetimibe or other ingredients of EZETIMIBE VIATRIS 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.

EZETIMIBE VIATRIS

Active ingredient(s): *ezetimibe*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking EZETIMIBE VIATRIS. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking EZETIMIBE VIATRIS.**

Where to find information in this leaflet:

1. Why am I taking EZETIMIBE VIATRIS?
2. What should I know before I take EZETIMIBE VIATRIS?
3. What if I am taking other medicines?
4. How do I take EZETIMIBE VIATRIS?
5. What should I know while taking EZETIMIBE VIATRIS?
6. Are there any side effects?
7. Product details

1. Why am I taking EZETIMIBE VIATRIS?

EZETIMIBE VIATRIS contains the active ingredient Ezetimibe. EZETIMIBE VIATRIS helps to lower cholesterol levels.

It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

EZETIMIBE VIATRIS may be taken alone or with other cholesterol-lowering medicines known as HMG-CoA reductase inhibitors (or statins), in addition to diet.

In people who have high levels of plant sterols in their blood (which doctors call sitosterolaemia), EZETIMIBE VIATRIS helps to lower these levels.

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.

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.

How EZETIMIBE VIATRIS works

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

EZETIMIBE VIATRIS works by decreasing the absorption of cholesterol in the small intestine. Statins lower cholesterol in a different way, by reducing the amount of cholesterol made in the liver.

EZETIMIBE VIATRIS adds to the cholesterol-lowering effect of statins.

For patients with heart disease and a history of a heart attack or hospitalisation for unstable angina (chest pain), EZETIMIBE VIATRIS combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

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

EZETIMIBE VIATRIS is not addictive.

2. What should I know before I take EZETIMIBE VIATRIS?

Warnings

Do not take EZETIMIBE VIATRIS if:

- you have an allergy to EZETIMIBE VIATRIS or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include
  - skin rash, itchiness;
  - shortness of breath;
  - swelling of the face, lips, mouth, tongue or throat.
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.
- If you take EZETIMIBE VIATRIS after the expiry date has passed, it may not work.

Do not take the EZETIMIBE VIATRIS together with statin if:

- you have active liver disease
- you are pregnant or breast feeding.

Do not take EZETIMIBE VIATRIS together with fenofibrate if:

- you have gall bladder disease.

If you are not sure whether you should start taking EZETIMIBE VIATRIS, talk to your doctor.

Check with your doctor if you:

- you have, or have had, any medical conditions, including liver disease or liver problems

  If you are prescribed EZETIMIBE VIATRIS with a statin, your doctor will do a blood test to make sure you have no problems with your liver.
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any EZETIMIBE VIATRIS.

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.

If there is a need to consider taking EZETIMIBE VIATRIS during pregnancy, your doctor will discuss the risks and benefits of taking it.

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

It is not known if EZETIMIBE VIATRIS passes into breast milk.

Use in Children and Adolescents

EZETIMIBE VIATRIS 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).

EZETIMIBE VIATRIS is not recommended in children under 10 years of age as there have been very few studies of its effects in these children.

Your doctor will assess whether if EZETIMIBE VIATRIS is suitable for your child. Depending on the pubertal development of your child, EZETIMIBE VIATRIS 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 EZETIMIBE VIATRIS, including:

- Certain fibrate medicines used to lower cholesterol levels, for example, gemfibrozil. However, the fibrate medicine fenofibrate can be taken with EZETIMIBE VIATRIS.

Some medicines may interfere with EZETIMIBE VIATRIS and affect how it works. Tell your doctor if you are taking the following:

- Bile acid sequestrants, such as colestyramine, used to lower cholesterol levels.
- Ciclosporin, used to suppress the immune system.
- Warfarin or fluindione, used to prevent blood clots.
- eltrombopag, used to increase your platelet count in your blood clots.

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

4. How do I take EZETIMIBE VIATRIS?

How much to take

- The recommended dose is 10 mg taken once a day. Swallow EZETIMIBE VIATRIS with a glass of water.
- Depending on your condition and ethnic background, your doctor will decide the most appropriate dose for you.
- Follow all directions given to you by your doctor and pharmacist carefully.

When to take EZETIMIBE VIATRIS

- EZETIMIBE VIATRIS should be taken at about the same time each day. It does not matter whether you take EZETIMIBE VIATRIS with food or on an empty stomach. However, take it about the same time each day.
- If you are taking a statin, EZETIMIBE VIATRIS can be taken at the same time as the statin.
- If you are taking a bile acid sequestrant, such as colestyramine, take your EZETIMIBE VIATRIS either at least two hours before or four hours after taking the bile acid sequestrant.

How to take EZETIMIBE VIATRIS

- Swallow each tablet whole with a glass of water
- 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 EZETIMIBE VIATRIS, your cholesterol levels may rise again.

If you forget to take EZETIMIBE VIATRIS

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(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much EZETIMIBE VIATRIS

If you think that you or anyone else has taken too much EZETIMIBE VIATRIS, urgent medical attention may be needed.

You should immediately:

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

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking EZETIMIBE VIATRIS?

Things you must do

Have your blood fats checked when your doctor says, to make sure EZETIMIBE VIATRIS is working.

Call your doctor straight away if you:

- become pregnant while taking EZETIMIBE VIATRIS.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking EZETIMIBE VIATRIS.

Tell your doctor, dentist or pharmacist you visit that you are taking EZETIMIBE VIATRIS.

Things you must not do

- Do not stop taking EZETIMIBE VIATRIS suddenly unless you have discussed it with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EZETIMIBE VIATRIS affects you.

EZETIMIBE VIATRIS may affect your ability to drive or operate machinery in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Excessive alcohol consumption may not be safe in patients taking EZETIMIBE VIATRIS.

Looking after your medicine

- Keep it in a cool dry place where the temperature stays below 25°C.

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.

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

When to discard your medicine

- If you no longer need to take it
- After the expiry date

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

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
Muscle/skeleton-related: • muscle spasms • neck pain • pain in arms and legs • back pain • elevations in some laboratory blood tests of muscle function **Gastrointestinal-related:** • nausea • diarrhoea • wind or excessive gas in the stomach or bowel • indigestion • heartburn • decreased appetite • dry mouth • abdominal pain • constipation **Liver-related:** • gallstones • inflammation of the gallbladder • elevations in some laboratory blood test of liver function **Heart and circulation-related:** • hot flush • high blood pressure • swelling, especially in the hands and feet **Skin-related:** • itching **Metabolism and nutrition-related:** • decreased appetite • inflammation of the pancreas	**Speak to your doctor if you have any of these less serious side effects.**

Less serious side effects	What to do
Head and nervous system-related: • dizziness • headache • tingling or numbness of the hands or feet **Mood related:** • depression **Respiratory related:** • cough **General conditions:** • unusual tiredness or weakness • fatigue • chest pain • pain	

Serious side effects

Serious side effects	What to do
• swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing If you have these side effects, you may have had a serious allergic reaction to EZETIMIBE VIATRIS. You may need urgent medical attention or hospitalisation. These side effects are very rare.	**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.**
• skin rash and hives • severe skin problems • dark coloured urine • light coloured bowel motions • yellowing of the skin and eyes • joint pain • bleeding or bruising more easily than normal • steady abdominal pain with nausea and vomiting • unexplained muscle aches, tenderness or weakness, not caused by exercise • On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage Serious side effects are rare.	**Tell your doctor immediately if you notice any of these side effects. These may be serious side effects and you may need urgent medical attention.**

In adolescent patients (10 to 17 years of age) there have been no studies longer than one year of the effect of taking EZETROL in combination with simvastatin on bone development, growth, social and emotional development, or fertility.

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.

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

EZETIMIBE VIATRIS is only available with a doctor's prescription.

What EZETIMIBE VIATRIS contains

Active ingredient (main ingredient)	Ezetimibe
Other ingredients (inactive ingredients)	croscarmellose sodium mannitol butyl hydroxy anisole magnesium stearate povidone sodium stearylfumarate sodium lauryl sulfate

Do not take EZETIMIBE VIATRIS if you are allergic to any of these ingredients.

What EZETIMIBE VIATRIS looks like

EZETIMIBE VIATRIS 10 mg is white to off-white, capsule-shaped tablet, debossed with “10” on one side and plain on the other side. (AUST R 396896 (blister) and AUST R 468268 (bottle))

Who distributes EZETIMIBE VIATRIS?

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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