

SCHEDULING STATUS: S4

NOVABE, 10 mg tablets

Ezetimibe

Contains sugar

Read all of this leaflet carefully before you start taking NOVABE

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

1. What NOVABE is and what it is used for

NOVABE contains the active substance ezetimibe 10 mg per tablet and belongs to a group of medicines called serum-cholesterol reducers.

NOVABE is a medicine used to lower increased cholesterol levels. NOVABE lowers total cholesterol, as well as LDL or “bad” cholesterol.

NOVABE works by reducing the cholesterol absorbed from your digestive tract.

NOVABE adds to the cholesterol-lowering effect of statins, a group of medicines that reduce the cholesterol your body makes by itself.

NOVABE is used in conjunction with diet, either alone, or with another cholesterol lowering medicine (statin).

2. What you need to know before you take NOVABE

Do not take NOVABE:

- if you are hypersensitive (allergic) to ezetimibe or to any other ingredients of NOVABE
- if you are pregnant or breastfeeding
- if you have moderate or severe liver problems
- if you are a child below the age of 10 years

Do not take NOVABE together with a statin if you have active liver disease or unexplained persistent elevations in liver enzymes.

Warnings and precautions

Tell your doctor or healthcare professional before taking NOVABE:

Take special care with NOVABE:

- if you are taking NOVABE with a statin, please refer to the Patient Information Leaflet for that particular medicine
- if you are taking other cholesterol lowering medicines
- your doctor should do a blood test before you start taking NOVABE with a statin, 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 NOVABE with a statin
- if you experience any unexplained muscle pain, tenderness or weakness, tell your doctor promptly
- if you are taking medicines called fibrates, the safety and efficacy of taking fibrates with NOVABE has not been established
- if you are taking a medicine called ciclosporin, your doctor may need to monitor ciclosporin levels in your blood

- if you are taking medicines for blood clotting

Children and adolescents

Do not give this medicine to children less than 10 years old because there is no information in this age group.

Do not give this medicine to children and adolescents (10 to 17 years of age) unless prescribed by a specialist because there are limited data on safety and efficacy.

Other medicines and NOVABE

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor or healthcare provider if you are taking any of the following medicines:

- fibrates, a medicine also used to lower cholesterol, it may increase levels of NOVABE (see ‘Take Special care with NOVABE’),
- antacids (medicines used to reduce the amount of acid such as cimetidine), it may decrease the rate of absorption of NOVABE,
- cholestyramine (also a medicine used to lower cholesterol) as it reduces the levels of NOVABE,
- ciclosporin (a medicine often used in organ transplant patients) as it may increase concentrations of NOVABE, patients receiving both medicines should be carefully monitored (see ‘Take Special care with NOVABE’)
- anticoagulants (medicines used to prevent blood clots such as warfarin or fluindione), patients receiving both medicines should be carefully monitored (see ‘Take Special care with NOVABE’).

NOVABE with food and drink

NOVABE can be taken with or without a meal.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking this medicine.

You should not take NOVABE if you are pregnant or breastfeeding your baby.

No data on fertility in humans are available.

Driving and using machines

NOVABE can cause dizziness.

It is not always possible to predict to what extent NOVABE may interfere with your daily activities. You should ensure that you do not engage in driving and using machines until you are aware of the measure to which NOVABE affects you.

NOVABE contains lactose monohydrate

NOVABE tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NOVABE.

3. How to take NOVABE

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

Always take NOVABE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will place you on an appropriate lipid-lowering diet and weight loss programme if necessary, this diet should be followed during your treatment with NOVABE.

The usual dose is one 10 mg tablet once daily, used alone or in combination with other cholesterol lowering medicines.

NOVABE can be taken at any time of the day, with or without food.

If your doctor has prescribed NOVABE along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, NOVABE should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Your doctor will tell you how long your treatment with NOVABE will last. If you have the impression that the effect of NOVABE is too strong or too weak, tell your doctor or pharmacist.

If you take more NOVABE than you should

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

Symptomatic and supportive measures should be employed in the treatment of a suspected overdose.

If you forget to take NOVABE

Do not take a double dose to make up for forgotten individual doses, just take your normal amount of NOVABE at the usual time the next day.

If you stop taking NOVABE

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

4. Possible side effects

NOVABE can have side effects.

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

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition.

If any of the following happens, stop taking NOVABE immediately and go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NOVABE.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects:

Side effects while taking NOVABE alone

Frequent side effects:

- abdominal pain, diarrhoea, flatulence
- headache, fatigue.

Less frequent side effects:

- increased liver enzyme levels, abnormal liver function tests
- cough
- indigestion, acid reflux, nausea
- joint pain, muscle spasms, neck pain
- decreased appetite
- hot flushes, high blood pressure
- chest pain, pain.

Additional side effects while taking NOVABE together with a statin

Frequent side effects:

- increased liver enzyme levels
- headache
- muscle pain.

Less frequent side effects:

- tingling or numbness in the hands or feet
- dry mouth, gastritis
- itching, rash, hives
- back pain, muscular weakness, pain in extremity
- unusual tiredness or weakness
- swelling, especially in the hands and feet.

Side effects while taking NOVABE together with fenofibrate

Frequent side effects:

- abdominal pain.

The following side effects have also been reported (post-marketing) with or without a statin:

- increased bleeding or bruising
- dizziness
- tingling or numbness in the hands or feet
- shortness of breath
- inflammation of pancreas (severe pain in abdomen and back)
- constipation
- raised red rash, sometimes with target-shaped lesions
- muscle pain, muscle weakness, muscle breakdown
- unusual tiredness or weakness
- allergic reactions including rash and hives
- hepatitis, gallstones or gallbladder inflammation (which may cause abdominal pain, nausea, vomiting)
- depression.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NOVABE.

5. How to store NOVABE

Store at or below 25 °C in the original package.

Do not remove blister from carton until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What NOVABE contains

- The active substance is ezetimibe.
- The other ingredients are: cellulose microcrystalline, croscarmellose sodium, crospovidone, hypromellose, lactose monohydrate, magnesium stearate and sodium laurylsulfate.

Contains sugar (lactose monohydrate), 62 mg per tablet.

What NOVABE looks like and contents of the pack

NOVABE is white to off-white, uncoated, capsule shaped bevelled edge tablets debossed with “E Z” on one side and “10” on the other side. The size is 8,1 mm x 4,1 mm.

NOVABE tablets are packaged in three-layer cold form laminate film (PVC/Al/OPA) and aluminium foil blister packs or clear PVC/PVdC and aluminium foil blister packs. The blisters are further packed into an outer carton.

Pack sizes: Each carton contains 30 tablets (3 blisters of 10 tablets each).

Holder of Certificate of Registration

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