

ZEKLEN®

Ezetimibe/Simvastatin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZEKLEN. 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 ZEKLEN 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 ZEKLEN is used for

ZEKLEN 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.

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 ZEKLEN works

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

ZEKLEN works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the liver. ZEKLEN does not help you lose weight.

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), ZEKLEN reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

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

ZEKLEN is not addictive.

Use in Children and Adolescents

ZEKLEN 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).

ZEKLEN 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 ZEKLEN is suitable for your child. Depending on the pubertal development of your child, ZEKLEN may not be suitable for him or her.

Before you take ZEKLEN

When you must not take it

Do not take ZEKLEN if:

- **you have an allergy to ZEKLEN 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.

- **you are pregnant or breast feeding.**

ZEKLEN 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 "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.

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

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant.**
ZEKLEN should not be used during pregnancy.
2. **you are breast-feeding.**
ZEKLEN should not be used while breast feeding.
3. **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.
4. **you are Asian.**
5. **you are taking niacin or a niacin-containing product.**

6. **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.

7. **you have kidney disease, diabetes or any other medical problems.**
8. **you drink alcohol regularly.**
9. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
10. **you 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.**

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

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 ZEKLEN. 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 used to treat certain fungal infections

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

Some medicines and ZEKLEN may interfere with each other. 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

These medicines may be affected by ZEKLEN, may affect how well it works, or may increase the risk of side effects with ZEKLEN. You may need different amounts of your

medicine, or you may need to take different medicines or take your medicines at different times.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ZEKLEN.

You should also tell any doctor who is prescribing a new medication for you that you are taking ZEKLEN.

How to take ZEKLEN

How much to take

Take ZEKLEN only when prescribed by your doctor.

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

The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one ZEKLEN 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 ZEKLEN 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 ZEKLEN with a glass of water.

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

They may differ from the information contained in this leaflet.

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

When to take it

ZEKLEN 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, ZEKLEN 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 ZEKLEN about the same time each day.

Taking ZEKLEN 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 ZEKLEN with other cholesterol lowering agents such as bile acid sequestrants.

If you are taking a bile acid sequestrant, such as colestyramine, take your ZEKLEN either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take it

ZEKLEN 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 ZEKLEN, your cholesterol levels may rise again.

If you forget to take it

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.

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 tablet, ask your pharmacist for some hints.

If you take too much (overdose)

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

While you are using ZEKLEN

Things you must do

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

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

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

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

Things you must not do

Do not give ZEKLEN 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 ZEKLEN causing liver problems.

Grapefruit juice should be avoided while taking ZEKLEN.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including ZEKLEN.

Be careful driving or operating machinery until you know how ZEKLEN affects you.

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

ZEKLEN 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 ZEKLEN. 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
- 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).

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 ZEKLEN).

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 ZEKLEN, 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.

Serious side effects are rare.

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
- Hot flush
- Hypertension
- Pain

These are the more common side effects of ZEKLEN 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
- Blurred vision and 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
- Gynaecomastia (breast enlargement in men) (very rare)
- Muscle rupture (very rare)
- Rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions) (very rare)

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 ZEKLEN 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.

After using ZEKLEN

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 ZEKLEN 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 ZEKLEN 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

ZEKLEN comes in four types of tablets:

- ZEKLEN 10/10 - 10mg Ezetimibe/10mg Simvastatin: White to off-white, capsule shaped, biconvex compressed tablet marked with "311".
- ZEKLEN 10/20 - 10mg Ezetimibe/ 20mg Simvastatin: White to off-white, capsule shaped, biconvex compressed tablet marked with "312".
- ZEKLEN 10/40 - 10mg Ezetimibe/ 40mg Simvastatin: White to off-white, capsule shaped, biconvex compressed tablet marked with "313".
- ZEKLEN 10/80 - 10mg Ezetimibe/ 80mg Simvastatin: White to off-white, capsule shaped, biconvex compressed tablet marked with "315".

A starter pack of ZEKLEN contains 5 or 10 tablets. A trade pack contains 30 tablets.

Ingredients

Active ingredient:

ZEKLEN 10/10 -
10mg ezetimibe/10mg simvastatin per tablet

ZEKLEN 10/20 -
10mg ezetimibe/20mg simvastatin per tablet

ZEKLEN 10/40 -
10mg ezetimibe/ 40mg simvastatin per tablet

ZEKLEN 10/80 -

10mg ezetimibe/ 80mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- citric acid monohydrate
- croscarmellose sodium
- hypromellose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- propyl gallate

ZEKLEN does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

ZEKLEN is supplied in Australia by:
Organon Pharma Pty Limited
Building A, 26 Talavera Road
MACQUARIE PARK NSW 2113

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This CMI leaflet was current at the time of printing. To check if it has been updated, please ask your pharmacist.

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