PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is to be supplied under doctor's prescription only

EZETIMIBE SANDOZ®

Tablets

Active substance and its amount:
Each tablet contains:
ezetimibe 10 mg

For a list of inactive ingredients please refer to 'Important information about some of the ingredients of Ezetimibe Sandoz' as well as section 6.

Read the entire leaflet carefully before using this medicine.
- This leaflet contains concise information about Ezetimibe Sandoz. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

1. WHAT IS EZETIMIBE SANDOZ USED FOR?

Ezetimibe Sandoz is intended for patients with:
Primary hypercholesterolemia:
Ezetimibe Sandoz administered with an HMG-CoA reductase inhibitor (statin) or alone are indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolemia.
Homozygous familial hypercholesterolemia (HoFH):
Ezetimibe Sandoz administered with a statin are indicated for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).
Homozygous sitosterolemia (Phytosterolemia): Ezetimibe Sandoz is indicated for use in patients with homozygous familial sitosterolemia.

Therapeutic group:
Ezetimibe is a member of a class of medicines called *CAI* (Cholesterol Absorption Inhibitors), which inhibits the intestinal absorption of cholesterol.

2. BEFORE YOU TAKE EZETIMIBE SANDOZ

Do not take Ezetimibe Sandoz:
- if you are allergic (hypersensitive) to ezetimibe or any of the other ingredients of Ezetimibe Sandoz (see also section 6).
- together with a statin, if you currently have liver problems.
- together with a statin, if you are pregnant or breast feeding.

If you use Ezetimibe Sandoz together with a statin, please read the package leaflet of that particular medicine.
If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Special warnings concerning use of Ezetimibe Sandoz
- Tell your doctor about all your medical conditions including allergies.
- Your doctor should refer you to do a blood test before you start taking Ezetimibe Sandoz 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 Ezetimibe Sandoz with a statin.

If you have moderate or severe liver problems, it is recommended not to use Ezetimibe Sandoz.

Children and adolescents
Do not give this medicine to children and adolescents (10 to 17 years of age) unless prescribed by a specialist, because there is limited data on safety and efficacy.
This medicine is not intended for children under age 10.

Other medicines and Ezetimibe Sandoz
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.
In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:
- ciclosporin (often used in organ transplant patients)
- medicines with an active ingredient to prevent the formation of blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- colestyramine (also used to lower cholesterol), because it affects the way Ezetimibe Sandoz works
- fibrates (also used to lower cholesterol). The safety and efficacy of the combined use of Ezetimibe Sandoz and certain cholesterol lowering medicines, the fibrates, have not been established.

Taking Ezetimibe Sandoz with food
You can take Ezetimibe Sandoz with or without food.

Pregnancy and breast-feeding
Do not take Ezetimibe Sandoz with a statin if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking Ezetimibe Sandoz with a statin, stop taking both medicines immediately and tell your doctor. There is no experience from the use of Ezetimibe Sandoz without a statin during pregnancy. Ask your doctor for advice before using Ezetimibe Sandoz if you are pregnant.
Do not take Ezetimibe Sandoz, with or without a statin, if you are breast-feeding, because it is not known whether the medicines are passed into breast milk.
Ask your doctor for advice.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ezetimibe Sandoz is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people may get dizzy after taking Ezetimibe Sandoz.

Important information about some of the ingredients of Ezetimibe Sandoz
Ezetimibe Sandoz 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 this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW DO YOU USE EZETIMIBE SANDOZ?

Always take Ezetimibe Sandoz exactly as your doctor has told you. Continue taking your other cholesterol lowering medicines unless your doctor tells you to stop. You should check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment.
Your doctor will determine the dosage and duration of the treatment.
Swallow the medicine with a small amount of water. Do not chew or crush the tablet.
Before starting Ezetimibe Sandoz, you should start a diet to lower your cholesterol. You should keep on this cholesterol lowering diet whilst taking Ezetimibe Sandoz.

The usually recommended dose is:
One Ezetimibe Sandoz 10 mg tablet by mouth once a day.

Do not exceed the recommended dose.
You can take Ezetimibe Sandoz at any time of the day. You can take it with or without food.

If your doctor has prescribed Ezetimibe Sandoz along with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of that particular medicine.
If your doctor has prescribed Ezetimibe Sandoz along with another medicine for lowering cholesterol containing the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take Ezetimibe Sandoz at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more Ezetimibe Sandoz than you should
Please contact your doctor or pharmacist.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take Ezetimibe Sandoz
Do not take a double dose to make up for a forgotten tablet, just take your normal amount of Ezetimibe Sandoz at the usual time the next day.

If you stop taking Ezetimibe Sandoz
Talk to your doctor or pharmacist because your cholesterol may rise again.

How can you contribute to the success of the treatment?
Complete the full course of treatment as instructed by the doctor. Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.
If you have any further question on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, Ezetimibe Sandoz can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

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

Allergic reactions, including swelling of the face, lips, tongue, and/or throat that <u>may</u> cause difficulty in breathing or swallowing (<u>which requires</u> treatment right away) have been reported in general use.
When used alone, the following side effects were reported:
<u>Common (may affect up to 1 in 10 patients):</u> abdominal pain, diarrhea, flatulence, feeling tired.
<u>Uncommon (may affect up to 1 in 100 patients):</u> elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function, cough, indigestion, heartburn, nausea, joint pain, muscle spasms, neck pain, decreased appetite, pain, chest pain, hot flush, high blood pressure.
When used with a statin, the following side effects were reported:
<u>Common (may affect up to 1 in 10 patients):</u> elevations in some laboratory blood tests of liver function (transaminases), headache, muscle pain, tenderness or weakness.
<u>Uncommon (may affect up to 1 in 100 patients):</u> tingling sensation, dry mouth, itching, rash, hives, back pain, muscle weakness, pain in arms and legs, unusual tiredness or weakness, swelling, especially in the hands and feet.
When used with fenofibrate, the following common side effect was reported: abdominal pain.
<u>Additionally, the following side effects have been reported:</u> dizziness, muscle aches, liver problems, allergic reactions including rash and hives, raised red rash, sometimes with target-shaped lesions (erythema multiforme), muscle pain, tenderness or weakness, muscle breakdown, gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting), inflammation of the pancreas often with severe abdominal pain, constipation, reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopaenia), tingling sensation, depression, unusual tiredness or weakness, shortness of breath.

If you experience side effects, or if one of the side effects worsens, or if you experience a side effect not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Reporting side effects
Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (<u>www.health.gov.il</u>) which refers to the online side effects reporting form, or by using the link: <u>https://sideeffects.health.gov.il</u>

5. HOW TO STORE EZETIMIBE SANDOZ?

Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use Ezetimibe Sandoz after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.

Store this medicine in the original package to protect from moisture, at a temperature not exceeding 25ºC.

Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ezetimibe Sandoz contains?
The active substance is ezetimibe. Each tablet contains 10 mg ezetimibe.
The other ingredients are:
Lactose monohydrate, Microcrystalline cellulose, Croscarmellose sodium, Hypromellose, Sodium lauryl sulfate, Magnesium stearate.
Ezetimibe Sandoz Tablets contain lactose:
Each tablet of Ezetimibe Sandoz 10 mg contains 67.50 mg lactose monohydrate.

What Ezetimibe Sandoz looks like and contents of the pack
Ezetimibe Sandoz tablets are white to almost white, oval tablets with debossing "SZ" on one side and "499" on the other side.
Each pack contains 30 tablets in blisters.

License Holder and Importer and address:
Novartis Israel LTD.,
P.O.Box 7126, Tel Aviv.

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Drug registration no. listed in the official registry of the Ministry of Health:
162-46-35587-00