PACKAGE LEAFLET

Package leaflet: Information for the patient

Ezetimibe/Atorvastatine Sandoz 10 mg/10 mg, filmomhulde tabletten
Ezetimibe/Atorvastatine Sandoz 10 mg/20 mg, filmomhulde tabletten
Ezetimibe/Atorvastatine Sandoz 10 mg/40 mg, filmomhulde tabletten
Ezetimibe/Atorvastatine Sandoz 10 mg/80 mg, filmomhulde tabletten

ezetimibe and atorvastatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] is a medicine to lower increased levels of cholesterol. [Nationally completed name] contains ezetimibe and atorvastatin.

[Nationally completed name] is used in adults to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, [Nationally completed name] raises levels of “good” cholesterol (HDL cholesterol).

[Nationally completed name] works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

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 are another form of fat in your blood that may increase your risk for heart disease.

Your doctor may prescribe [Nationally completed name] if you are already taking both atorvastatin and ezetimibe at the same dose level, as substitution therapy, in addition to your cholesterol lowering diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia heterozygous and homozygous familial and non-familial) or elevated fat levels in your blood (mixed hyperlipidaemia)

[Nationally completed name] does not help you lose weight.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if

- you are allergic to atorvastatin, ezetimibe or any of the other ingredients of this medicine (listed in section 6)
- you have or have ever had a disease that affects the liver
- you have had any unexplained abnormal blood tests for liver function
- you are a woman able to have children and are not using reliable contraception
- you are pregnant, trying to become pregnant or are breast-feading
- you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name] if

- you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- you have kidney problems
- you have an under-active thyroid gland (hypothyroidism)
- you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other “statin” or fibrate” medicines)
- you have or have had myasthenia (a disease with general muscle weakness including in some

cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4)
- You are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Atorvastatin/Ezetimibe containing medicines can lead to serious muscle problems (rhabdomyolysis)
- you regularly drink a large amount of alcohol
- you have a history of liver disease
- you are older than 70 years

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking [Nationally completed name]. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. Atorvastatin is known to cause muscle problems, and cases of muscle problems have also been reported with ezetimibe.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Check with your doctor or pharmacist before taking [Nationally completed name]
- if you have severe respiratory failure.

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before taking [Nationally completed name] because your doctor will need to carry out a blood test before and possible during your treatment to predict your risk of muscle-related side effects. The risk of muscle-related side effects, e.g. rhabdomyolysis (breakdown of damaged skeletal muscle), is known to increase when certain medicines are taken at the same time (see section 2 “Other medicines and [Nationally completed name]”).

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Tell your doctor about all medical conditions including allergies.

Children
[Nationally completed name] is not recommended for children and adolescents.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Fibrates (medicines for lowering cholesterol) should be avoided while taking [Nationally completed name].

A medicine that contains the active substances ledipasvir and sofosbuvir. This medicine is given to treat chronic (long-term) hepatitis C virus infection in adults and children 3 years of age and older. Taking [Nationally completed name] with this medicine may make any side effects worse. Your doctor may need to give you a different medicine or adjust the dose of medicine you are taking.

There are some medicines that may change the effect of [Nationally completed name] or the effect of other medicines may be changed by [Nationally completed name] (see section 3). This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side effects, including the important muscle wasting condition known as "rhabdomyolysis" described in section 4:

- ciclosporin (a medicine often used in organ transplant patients)
- erythromycin, clarithromycin, telithromycin, fusidic acid, rifampicin (medicines for bacterial infections)
- ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole (medicines for fungal infections)
- gemfibrozil, other fibrates, nicotinic acid, derivatives, colestipol, colestyramine (medicines for regulating lipid levels)
- some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem
- digoxin, verapamil, amiodarone (medicines to regulate your heart rhythm)
    - letermovir, a medicine that helps stop you from getting ill from cytomegalovirus
- medicines used in the treatment of HIV, e.g., ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir, etc. (medicines for AIDS)
    - some medicines used in the treatment of hepatitis C, e.g., telaprevir, boceprevir and the combination of elbasvir, grazoprevir
    - daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteraemia).
- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart [Nationally completed name]. Taking [Nationally completed name] with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

- Other medines known to interact with the combination product
    - ➢ oral contraceptives (medicines for preventing pregnancy)
    - ➢ stiripentol (an anticonvulsant medicine for epilepsy)
    - ➢ cimetidine (a medicine used for heartburn and peptic ulcers)
    - ➢ phenazone (a painkiller)
    - ➢ antacids (indigestion products containing aluminium or magnesium)
    - ➢ warfarin, phenrprocoumon, acenocoumarol or fluindione (medicines to prevent

blood clots)
- colchicine (used to treat gout)
- St John´s Wort (a medicine to treat depression)

[Nationally completed name] with food and alcohol
See section 3 for instructions on how to take [Nationally completed name]. Please note the following:

Grapefruit juice
Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of the combination product.

Alcohol
Avoid drinking too much alcohol while taking this medicine. See section 2 "Warnings and precautions" for details.

Pregnancy, breast-feeding and fertility

Do not take [Nationally completed name] if you are pregnant, are trying to become pregnant or think you may be pregnant.
Do not take [Nationally completed name] if you are able to become pregnant unless you use reliable contraceptive measures. If you get pregnant while taking [Nationally completed name], stop taking it immediately and tell your doctor.

Do not take [Nationally completed name] if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
[Nationally completed name] 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 [Nationally completed name]. If you feel dizzy after taking this medicine do not drive or use machines.

[Nationally completed name] contains 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.

[Nationally completed name] contains sodium
[Nationally completed name] contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ´sodium-free`.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor has told you. Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk status. Check with your doctor or pharmacist if you are not sure.

- Before starting [Nationally completed name], you should be on a diet to lower your cholesterol
- You should stay on this cholesterol-lowering diet while taking [Nationally completed name]

How much to take
The recommended dose is one [Nationally completed name] tablet once a day preferably always at the same time. The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water).

When to take
Take [Nationally completed name] at any time of the day. You can take it with or without food.

If your doctor has prescribed [Nationally completed name] along with colestyramine or any other bile acid sequestrant (medicines for lowering cholesterol), you should take [Nationally completed name] at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more [Nationally completed name] than you should
Please contact your doctor or pharmacist.

If you forget to take [Nationally completed name]
Do not take a double dose to make up for a forgotten tablet. Just take your normal dose at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department and take your tablets with you.

- serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever; skin rash with pink-red blotches especially on palms of hands or soles of feet,

which may blister
- muscle weakness, tenderness, pain, rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature if may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)

You should consult your doctor as soon as possible if you experience problems with unexpected or unusual bleeding or bruising, because this may be suggestive of a liver complaint.

Other possible side effects with [Nationally completed name]:

Common: (may effect up to 1 in 10 people)
- Inflammation of the nasal passage, pain in the throat, nose bleed,
- Allergic reactions,
- Increasing blood glucose level, diabetic patients should monitor their blood glucose level,
- Headache,
- Nausea, constipation, flatulence, diarrhoea, indigestion, abdominal pain,
- Pain in the pharynx and/or larynx,
- Pain of the joints and/or hands or feet, back pain, muscle pain (myalgia), muscle spasm, joint swelling,
- Elevations in some laboratory blood tests of muscle function (creatine kinase (CK)),
- Abnormal liver function test results, elevations in some laboratory blood tests of liver function (transaminases),
- Feeling tired.

Uncommon: (may affect up to 1 in 100 people)
- Swellings due to an allergic reaction,
- Reduced blood glucose level, diabetic patients should monitor their blood glucose level,
- Loss of appetite, weight gain,
- Cough,
- Muscle weakness, neck pain, chest pain,
- Hot flashes, high blood pressure,
- Vomiting,
- Belching,
- Inflammation of the pancreas and the liver,
- Heartburn,
- Inflammation of the stomach membranes,
- Dry mouth,
- Redness of the skin, hives, skin rash, itching,
- Hair loss,
- Nightmares, difficulty sleeping,
- Dizziness,
- Numbness,

- Impaired sense of taste,
- Amnesia,
- Local abnormal sensations,
- Blurred vision,
- Ringing in your ears,
- Feeling of general discomfort, uneasiness or pain,
- Weakness,
- Increased liver enzyme gamma-glutamyltransferase,
- Positive urine test on white blood cells.

Rare: (may effect up to 1 in 1000 people)
- Reduction of blood platelets,
- Swelling of the lower layer of skin tissue of the face, tongue, throat, abdomen, arms or legs (angioneurotic oedema)
- Widespread rash forming sharply demarcated red patches or rash with blisters and pealing skin, particularly around the mouth, nose, eyes and genitals due to an allergic reaction
- Inflammation of the skeletal muscle, inflammation of the tendon sometimes complicated by rupture, muscle weakness due to a loss of skeletal muscle fibers,
- Visual disturbances,
- Yellowing of the skin and of the whites of the eyes.

Very rare: (may effect up to 1 in 10000 people)
- Anaphylactic shock by allergic reaction,
- Hearing loss,
- Liver failure,
- Increase of the size of male breasts.

Unknown frequency (that cannot be estimated from the available data) are
- Allergic reaction including rash and swelling of the lower layers of the skin,
- Shortness of breath, inflammation of the gall bladder, gallstones,
- Physical weakness and loss of strength, loss of muscle tissue by auto-immune antibodies,
- Depression,
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing),
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience 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.

Additionally, the following side effects have been reported during post-marketing for some statins (medicines used to lower cholesterol):
- Breathing problems including persistent cough and/or shortness of breath or fever,
  - Diabetes: this is more likely if you have high levels of sugars and fats in your blood, are

overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Sexual difficulties.

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains
{[Nationally completed name]} 10 mg/ 10 mg: each film-coated tablet contains 10 mg of ezetimibe and 10 mg atorvastatin (as calcium trihydrate).
{[Nationally completed name]} 10 mg/ 20 mg: each film-coated tablet contains 10 mg of ezetimibe and 20 mg atorvastatin (as calcium trihydrate).
{[Nationally completed name]} 10 mg/ 40 mg: each film-coated tablet contains 10 mg of ezetimibe and 40 mg atorvastatin (as calcium trihydrate).
{[Nationally completed name]} 10 mg/ 80 mg: each film-coated tablet contains 10 mg of ezetimibe and 80 mg atorvastatin (as calcium trihydrate).

The other ingredients are:

Tablet core:
cellulose microcrystaline 101 (E460), mannitol (E 421), calcium carbonate (E170), croscamellose sodium (E468), hydroxypropylcellulose (E463), polysorbate 80 (E433), iron oxide yellow (E172), magnesium stearate (E470b), povidone K29/32 (E1201), sodium laurilsulfate (E487).

Tablet Coating
[Nationally completed name] 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg - Opadry White OY-L-28900 consisting of:
Lactose monohydrate

Hypromellose 2910 (E464)
Titanium dioxide (E171)
Macrogol 4000 (E1521)

[Nationally completed name] 10 mg/80 mg - DrCoat FCU consisting of:
Hypromellose 2910
Titanium dioxide (E171)
Talc (E553b)
Macrogol 400
Iron oxide yellow (E172)

What [Nationally completed name] looks like and contents of the pack

{[Nationally completed name]} 10 mg/ 10 mg film-coated tablets: White, round, biconvex film coated tablets, with diameter 8.1 mm approximately.

{[Nationally completed name]} 10 mg/ 20 mg film-coated tablets: White, ovaloid, biconvex film coated tablets, with dimensions 11.6 x 7.1 mm approximately.

{[Nationally completed name]} 10 mg/ 40 mg film-coated tablets: White, capsule shape, biconvex film coated tablets, with dimensions 16.1 x 6.1 mm approximately.

{[Nationally completed name]} 10 mg/ 80 mg film-coated tablets: Yellow, oblong, biconvex film coated tablets, with dimensions 19.1 x 7.6 mm approximately.

[Nationally completed name] 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg film-coated tablets
OPA/Al/PVC//Al blisters containing 10, 30, 90 and100 film-coated tablets.
OPA/Al/PVC//Al perforated unit-dose blisters of 10 × 1, 30 × 1, 90 × 1 and 100 × 1 film-coated tablets.

[Nationally completed name] 10 mg/80 mg film-coated tablets
OPA/Al/PVC//Al blisters containing 10, 30, multipack containing 90 (2 packs of 45) & multipack containing 100 (2 packs of 50) film-coated tablets.
OPA/Al/PVC//Al perforated unit-dose blisters of 10 x 1, 30 x 1, multipack containing 90 x 1 (2 packs of 45 x 1) & multipack containing 100 x 1 (2 packs of 50 x 1) film-coated tablets.

Not all pack sizes may be marketed

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten
Elpen Pharmaceutical Co. Inc.

Marathonos Ave. 95
Pikermi Attiki, 19009
Griekenland

ELPEN Pharmaceutical Co. Inc.
Zapani, Block 1048
Keratea, 190 01
Griekenland

Lek Pharmaceuticals d.d.
Verovškova ulica 57
Ljubljana, 1526
Slovenie

In het register ingeschreven onder:
Ezetimibe/Atorvastatine Sandoz 10 mg/10 mg, filmomhulde tabletten - RVG 126886
Ezetimibe/Atorvastatine Sandoz 10 mg/20 mg, filmomhulde tabletten - RVG 126887
Ezetimibe/Atorvastatine Sandoz 10 mg/40 mg, filmomhulde tabletten - RVG 126888
Ezetimibe/Atorvastatine Sandoz 10 mg/80 mg, filmomhulde tabletten - RVG 126889

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Ezetimibe/Atorvastatine Sandoz 10 mg/10 mg, filmomhulde tabletten
	Ezetimibe/Atorvastatine Sandoz 10 mg/20 mg, filmomhulde tabletten
	Ezetimibe/Atorvastatine Sandoz 10 mg/40 mg, filmomhulde tabletten
	Ezetimibe/Atorvastatine Sandoz 10 mg/80 mg, filmomhulde tabletten
Oostenrijk	Ezetimib/Atorvastatin - 1 A Pharma 10 mg/10 mg Filmtabletten
	Ezetimib/Atorvastatin - 1 A Pharma 10 mg/20 mg Filmtabletten
	Ezetimib/Atorvastatin - 1 A Pharma 10 mg/40 mg Filmtabletten
	Ezetimib/Atorvastatin - 1 A Pharma 10 mg/80 mg Filmtabletten
België	Ezetimibe/Atorvastatin Sandoz 10 mg/10 mg filmomhulde tabletten
	Ezetimibe/Atorvastatin Sandoz 10 mg/20 mg filmomhulde tabletten
	Ezetimibe/Atorvastatin Sandoz 10 mg/40 mg filmomhulde tabletten
	Ezetimibe/Atorvastatin Sandoz 10 mg/80 mg filmomhulde tabletten
Estland	Ezetimibe/Atorvastatin Sandoz
Griekenland	Scioplar
Hongarije	TULIP Combi 10 mg/10 mg filmom obložene tablete
	TULIP Combi 10 mg/20 mg filmom obložene tablete
	TULIP Combi 10 mg/40 mg filmom obložene tablete
	TULIP Combi 10 mg/80 mg filmom obložene tablete
Litouwen	Ezetimibe/Atorvastatin10 mg/20 mg plėvele dengtos tabletės
	Ezetimibe/Atorvastatin10 mg/40 mg plėvele dengtos tabletės

Letland	Ezetimibe/Atorvastatin Sandoz 10 mg/20 mg apvalkotās tabletes
	Ezetimibe/Atorvastatin Sandoz 10 mg/40 mg apvalkotās tabletes
Portugal	Atorvastatina + Ezetimiba Sandoz
Roemenië	COLEATEZ 10 mg/10 mg comprimate filmate
	COLEATEZ 10 mg/20 mg comprimate filmate
	COLEATEZ 10 mg/40 mg comprimate filmate
	COLEATEZ 10 mg/80 mg comprimate filmate
Slovenië	Tulip Combi 10 mg/10 mg filmsko obložene tablete
	Tulip Combi 10 mg/20 mg filmsko obložene tablete
	Tulip Combi 10 mg/40 mg filmsko obložene tablete
	Tulip Combi 10 mg/80 mg filmsko obložene tablete

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.