PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LIPTRUZET® 10/10 Film-coated Tablets

LIPTRUZET® 10/20 Film-coated Tablets

LIPTRUZET® 10/40 Film-coated Tablets

ezetimibe and atorvastatin

Contains sugar:

Each 10/10 film-coated tablet contains 153 mg of lactose monohydrate.

Each 10/20 film-coated tablet contains 179 mg of lactose monohydrate.

Each 10/40 film-coated tablet contains 230 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking LIPTRUZET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- LIPTRUZET 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.
- 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.

What is in this leaflet

1. What LIPTRUZET is and what it is used for
2. What you need to know before you take LIPTRUZET
3. How to take LIPTRUZET
4. Possible side effects
5. How to store LIPTRUZET

6. Contents of the pack and other information

1. What LIPTRUZET is and what it is used for

LIPTRUZET is a medicine to lower increased levels of cholesterol (wax substance needed to build healthy cells, and, in case of high levels, can increase your risk of heart disease). LIPTRUZET contains ezetimibe (cholesterol-lowering medication) and atorvastatin (a type of medicine that blocks an enzyme [protein] needed by the body to make cholesterol, and this reduces the amount of cholesterol in the blood).

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

LIPTRUZET 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.

LIPTRUZET is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

LIPTRUZET is used in addition to your cholesterol-lowering diet if you have:

- a raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial {transmitted from parent to child} and non-familial]) or elevated cholesterol, high triglycerides, and often accompanied by low HDL (mixed hyperlipidaemia)
    - that is not well controlled with a statin (class of medicine used to lower cholesterol) alone;
    - for which you have used a statin and ezetimibe as separate tablets.
- a hereditary illness (homozygous familial hypercholesterolaemia [rare life-threatening condition characterised by markedly elevated circulating levels of low-density lipoprotein cholesterol and accelerated, premature atherosclerotic cardiovascular disease]) that increases the cholesterol level in your blood. You may also receive other treatments.
- heart disease. LIPTRUZET reduces the risk of heart attack, stroke, surgery to increase heart blood flow or hospitalisation for chest pain.

LIPTRUZET does not help you lose weight.

2. What you need to know before you take LIPTRUZET

Do not take LIPTRUZET if:

- you are allergic to ezetimibe, atorvastatin 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 breastfeeding
- you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.

Warnings and precautions

Talk to your doctor or pharmacist before taking LIPTRUZET. Take special care with LIPTRUZET 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 regularly drink a large amount of alcohol
- you have a history of liver disease
- you are older than 70 years
- you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product
- 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 LIPTRUZET can lead to serious muscle problems (rhabdomyolysis [A breakdown of muscle tissue that results in the release of a protein {myoglobin} into the blood. Myoglobin can damage the kidneys]).

Tell your doctor if 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, including atorvastatin as contained in LIPTRUZET, may lead to occurrence of or aggravate these conditions.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness or weakness while taking LIPTRUZET. Atorvastatin and ezetimibe are known to cause muscle problems.

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.

Also, check with your doctor or pharmacist before taking LIPTRUZET:

– if you have severe respiratory failure.

If any of these apply to you (or you are not sure), your doctor will need to carry out blood tests before and possibly during your LIPTRUZET treatment to predict your risk of muscle-related side effects. The risk of muscle-related side effects, e.g. rhabdomyolysis, is known to increase when certain medicines are taken at the same time (see section 2 “Other medicines and LIPTRUZET”).

While you are on this medicine your doctor will also 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,
- you are overweight and
- you have high blood pressure.

Tell your doctor about all your medical conditions including allergies.

The combined use of LIPTRUZET and fibrates (medicines for lowering cholesterol) should be avoided since the combined use of LIPTRUZET, and fibrates has not been studied.

Children

LIPTRUZET is not recommended for children and adolescents.

Other medicines and LIPTRUZET

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

There are some medicines that may change the effect of LIPTRUZET, or their effect may be changed by LIPTRUZET (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, cholestyramine (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)
- medicines used in the treatment of HIV/AIDS, e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir, etc.
- 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 LIPTRUZET. Taking LIPTRUZET with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.**
- Other medicines known to interact with LIPTRUZET
  - 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, phenprocoumon, acenocoumarol or fluindione (medicines to prevent blood clots)
  - colchicine (used to treat gout)
  - St John's wort (a medicine to treat depression).

LIPTRUZET with food and alcohol

See section 3 for instructions on how to take LIPTRUZET. 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 LIPTRUZET.

Alcohol

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

Pregnancy and breastfeeding

Do not take LIPTRUZET if you are pregnant, are trying to get pregnant or think you may be pregnant.

Do not take LIPTRUZET if you are able to become pregnant unless you use reliable contraceptive measures. If you get pregnant while taking LIPTRUZET, stop taking it immediately and tell your doctor.

Do not take LIPTRUZET if you are breastfeeding.

The safety of LIPTRUZET during pregnancy and breastfeeding has not yet been proven.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

LIPTRUZET 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 LIPTRUZET, therefore caution should be exercised when driving or using machinery.

LIPTRUZET contains lactose

LIPTRUZET 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.

3. How to take LIPTRUZET

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

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 LIPTRUZET, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol-lowering diet while taking LIPTRUZET.

How much to take

The recommended dose is one LIPTRUZET tablet by mouth once a day.

When to take

Take LIPTRUZET at any time of the day. You can take it with or without food.

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

If you take more LIPTRUZET than you should

Please contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LIPTRUZET

Do not take an extra dose; just take your normal amount of LIPTRUZET 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

LIPTRUZET can cause side effects.

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.

- 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 and 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 or rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it 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.

The following common side effects were reported (may affect up to 1 in 10 people):

- diarrhoea
- muscle aches.

The following uncommon side effects were reported (may affect up to 1 in 100 people):

- the flu
- depression; trouble sleeping; sleep disorder
- dizziness; headache; tingling sensation
- slow heartbeat
- hot flush
- shortness of breath
- abdominal pain; abdominal bloating; constipation; indigestion; flatulence; frequent bowel movements; inflammation of the stomach; nausea; stomach discomfort; upset stomach
- acne; hives (itchy, raised, skin-coloured welts on the skin's surface)
- joint pain; back pain; leg cramps; muscle fatigue, spasms or weakness; pain in arms and legs

- unusual weakness; feeling tired or unwell; swelling, especially in the ankles (oedema)
- elevations in some laboratory blood tests of liver or muscle creatine kinase (CK) function
- weight gain.

Additionally, the following side effects have been reported in people taking LIPTRUZET, or ezetimibe or atorvastatin tablets:

- allergic reactions including swelling of the face, lips, tongue and/or throat (angioedema) that may cause difficulty in breathing or swallowing (which requires treatment immediately)
- raised red rash, sometimes with target-shaped lesions
- liver problems
- cough
- heartburn
- decreased appetite; loss of appetite
- high blood pressure
- skin rash and itching; allergic reactions including rash and hives
- tendon injury
- gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- inflammation of the pancreas often with severe abdominal pain
- reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia)
- inflammation of the nasal passages; nosebleed
- neck pain; pain; chest pain; pain in the throat
- increases and decreases in blood sugar levels (if you have diabetes you should continue with monitoring of your blood sugar levels)
- having nightmares (disturbing dream associated with negative feelings, such as anxiety or fear that awakens you)
- numbness or tingling in the fingers and toes
- reduction of sensation to pain or touch

- change in sense of taste; dry mouth
- loss of memory
- ringing in the ears and/or head; hearing loss
- vomiting
- belching (expelling air from the stomach through the mouth)
- hair loss
- raised temperature
- urine tests that are positive for white blood cells
- blurred (the things you see do not look sharp and clear) vision; visual disturbances
- gynaecomastia (breast enlargement in men).

Possible side effects reported with some statins

- sexual difficulties (erectile dysfunction)
- depression (mood disorder that causes a persistent feeling of sadness and loss of interest)
- 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
- muscle pain, tenderness or weakness that is constant and particularly if, at the same time, you feel unwell or have a high temperature that may not go away after stopping LIPTRUZET.
- Contact your doctor if you experience weakness in your arms or legs that worsens after periods of activity, difficulty swallowing or shortness of breath (symptoms of myasthenia gravis), or double vision or drooping of your eyelids (symptoms of ocular myasthenia).

The following side effects were reported with frequency not known (frequency cannot be estimated from the available data):

- myasthenia gravis (a disease causing general muscle weakness)
- ocular myasthenia (a disease causing eye muscle weakness).

Contact your doctor promptly if you experience unexplained muscle pain, tenderness or weakness while taking LIPTRUZET. Atorvastatin and ezetimibe are known to cause muscle problems.

Reporting of side effects

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of LIPTRUZET.

5. How to store LIPTRUZET

- Store at or below 30 °C.
- Store in the original package in order to protect from oxygen.
- Keep this medicine out of the sight and reach of children.
- Do not take LIPTRUZET after the expiry date stated on the carton or container after EXP.: The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What LIPTRUZET contains

The active substances are ezetimibe and atorvastatin. Each film-coated tablet contains 10 mg ezetimibe and 10 mg, 20 mg or 40 mg atorvastatin (as atorvastatin calcium trihydrate).

The other ingredients are calcium carbonate; silica, colloidal anhydrous; croscarmellose sodium; hydroxypropyl cellulose; lactose monohydrate; magnesium stearate; cellulose, microcrystalline; polysorbate 80; povidone; sodium lauryl sulphate.

The film-coating contains: hypromellose, macrogol 8000, titanium dioxide (E171), talc.

What LIPTRUZET looks like and contents of the pack

Capsule-shaped, biconvex, film-coated tablets, white to off white.

LIPTRUZET 10/10 Tablets: “257” debossed on one side.

LIPTRUZET 10/20 Tablets: “333” debossed on one side.

LIPTRUZET 10/40 Tablets: “337” debossed on one side.

Pack sizes:

Packs of 30 film-coated tablets in nitrogen-purged aluminium/aluminium (oPA-Al-PVC cavity with Al lidding) blisters, in 3 strips of 10 tablets.

Holder of Certificate of Registration

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