

LIVAZEBE[®] Film-coated Tablets 2 mg/10 mg

LIVAZEBE[®] Film-coated Tablets 4 mg/10 mg

Pitavastatin Calcium (2.0 mg or 4.0 mg) and Ezetimibe (10 mg)

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What LIVAZEBE is used for

LIVAZEBE is a medicine used to correct the levels of fat (lipid) in your blood, the most common of which is cholesterol.

LIVAZEBE is for patients who cannot control their cholesterol levels by diet alone. You should continue following a cholesterol-lowering diet while taking this medicine.

LIVAZEBE is used in addition to your cholesterol-lowering diet if:

- you have high cholesterol levels in your blood (primary hypercholesterolemia including heterozygous familial hypercholesterolemia).
- you have the inherited condition that causes very high cholesterol (homozygous familial hypercholesterolemia) and are also receiving a non-drug treatment that removes cholesterol from your blood (LDL apheresis) or when such treatment is not feasible.

How LIVAZEBE works

LIVAZEBE contains two active substances: pitavastatin and ezetimibe. LIVAZEBE works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol produced in your body.

Before you use LIVAZEBE

- When you must not use it

Do not take LIVAZEBE:

- if you are allergic to pitavastatin or ezetimibe or any of the other

ingredients of this medicine (see "Product Description").

- if you have serious liver problems.
- if you are receiving cyclosporine.
- if you are or may be pregnant and breast-feeding.

If you are not sure, talk to your doctor or pharmacist before taking LIVAZEBE.

- Pregnancy and breastfeeding

Do not take LIVAZEBE if you are pregnant or breastfeeding. If you are trying to become pregnant, talk to your doctor before taking LIVAZEBE. If you are a woman who is able to have children, you must use a reliable contraceptive method, while taking LIVAZEBE. Stop taking LIVAZEBE and see a doctor straight away if you become pregnant while taking LIVAZEBE. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breastfeeding.

- Before you start to use it

Warnings and precautions:

Talk to your doctor or pharmacist before using LIVAZEBE and during treatment, if you have any of the following signs or symptoms:

- you have ever had thyroid problems.
- you have a personal or family history of muscle problems.
- you have ever had muscle problems when taking other cholesterol-lowering medicines (e.g. statins or fibrates).
- you drink large amounts of alcohol.
- you have ever had a condition that causes muscle weakness, such as:
 - Myasthenia gravis (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.
 - Immune-mediated necrotizing myopathy (presence of proximal muscle weakness, commonly

involving muscles of upper and/or lower limbs).

- you have ever had kidney problems.
- you have ever had liver problems.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking LIVAZEBE.

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.

LIVAZEBE contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Concomitant administration of LIVAZEBE with cyclosporine should be avoided.

Precaution should be taken during concomitant administration of LIVAZEBE with fibrates (e.g. bezafibrate), nicotinic acid, anion exchange resins (e.g. colestimide, cholestyramine), erythromycin, rifampicin, coumarin anticoagulants (e.g. warfarin).

How to use LIVAZEBE

- How much to use

Always take LIVAZEBE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

In general for adult patients, 1 tablet of LIVAZEBE (2 mg/10 mg or 4 mg/10 mg of pitavastatin calcium/ezetimibe) is orally administered once daily after a meal.

LIVAZEBE[®] Film-coated Tablets 2 mg/10 mg

LIVAZEBE[®] Film-coated Tablets 4 mg/10 mg

Pitavastatin Calcium (2.0 mg or 4.0 mg) and Ezetimibe (10 mg)

- When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

Use LIVAZEBE as instructed by your doctor until your doctor tells you to stop.

- If you forget to use it

Do not worry, just take your next dose at the correct time. Do not take a double dose to make up for the one you have missed. If you are unsure about anything, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more LIVAZEBE than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you. The treatment should be symptomatic and supportive.

While you are using LIVAZEBE

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the healthcare professionals treating you that you are taking LIVAZEBE.

Tell your doctor immediately if you become pregnant or breast-feeding while taking LIVAZEBE.

Your doctor may do regular cholesterol checks.

- Things you must not do

Do not stop taking LIVAZEBE without the advice of your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist. Do not take any new medicines without consulting your doctor.

Do not give LIVAZEBE to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

If you feel sleepy and/or dizzy, do not drive or operate machines until these side effects have gone away.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- Frequency Common (affects at least 1 in 100 people to less than 1 in 10 people) :
elevations in laboratory blood tests of liver function (ALT)
- Frequency Uncommon (affects at least 1 in 1000 people to less than 1 in 100 people) :
elevations in laboratory blood tests of liver (γ-GTP) and muscle (CK) function, protein in urine, increases in white blood cell count (leucocytosis)

Stop taking LIVAZEBE and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- Hypersensitivity symptoms including severe allergic reactions, swelling of the face, lips, tongue or throat, and rash.
- Rhabdomyolysis characterized by muscle pain, feelings of weakness, fever or reddishbrown urine.
- Immune-mediated necrotizing myopathy characterized by general muscle weakness commonly involving the muscles of upper and/or lower limbs.
- Liver problems which may cause yellowing of skin and eyes (jaundice)
- Trouble stopping bleeding
- Interstitial pneumonia characterized by fever, cough, and shortness of breath
- Myasthenia gravis (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness)

If you have muscle problems that do not go away even after your doctor has told you to stop taking LIVAZEBE, please refer to your doctor. Your doctor may do

further tests to diagnose the cause of your muscle problems.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of LIVAZEBE

- Storage

Store below 30°C in the original package. Protect from moisture and light after opening the aluminium-laminated bag.

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister and carton.

- Disposal

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.

Product Description

- What it looks like

LIVAZEBE Film-coated tablets are supplied in packs of 30.

LIVAZEBE 2 mg/10 mg: white, round, film-coated tablets with a diameter of approximately 8.1 mm, a thickness of approximately 4.4 mm and a weight of approximately 218 mg, debossed with "Kowa 221" on one side.

LIVAZEBE 4 mg/10 mg: light yellow, round, film-coated tablets with a diameter of approximately 8.1 mm, a thickness of approximately 4.4 mm and a weight of approximately 218 mg, debossed with "Kowa 222" on one side.

- Ingredients

- Active ingredients

- Pitavastatin Calcium (as hydrate)
- Ezetimibe

- Other ingredients

Tablet core:

LIVAZEBE[®] Film-coated Tablets 2 mg/10 mg

LIVAZEBE[®] Film-coated Tablets 4 mg/10 mg

Pitavastatin Calcium (2.0 mg or 4.0 mg) and Ezetimibe (10 mg)

Lactose Hydrate, Crospovidone,
Hypromellose, Magnesium
Aluminometasilicate, Microcrystalline
Cellulose, Povidone, Croscarmellose
Sodium, Sodium Lauryl Sulfate,
Magnesium Stearate

LIVAZEBE Film-coated Tablets 2
mg/10 mg:
Coating layer:
Hypromellose, Titanium Oxide, Triethyl
Citrate, Light Anhydrous Silicic Acid,
Carnauba Wax

LIVAZEBE Film-coated Tablets 4
mg/10 mg:
Coating layer:
Hypromellose, Titanium Oxide, Triethyl
Citrate, Light Anhydrous Silicic Acid,
Yellow Ferric Oxide, Carnauba Wax

- MAL number:

LIVAZEBE Film-coated Tablets 2
mg/10 mg: MAL XXXXXXXX

LIVAZEBE Film-coated Tablets 4
mg/10 mg: MAL XXXXXXXX

Manufacturer

Kowa Company, Ltd., Nagoya Factory
18-57, Hatooka 2-chome, Kita-ku,
Nagoya, Aichi, JAPAN

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm
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47301 Petaling Jaya, Selangor,
Malaysia.

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20/4/2026

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