

LIVALO Film-Coated Tablets 2mg

LIVALO Film-Coated Tablets 4mg

Pitavastatin Calcium (as hydrate) (2.0 mg or 4.0mg of pitavastatin calcium)

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What LIVALO is used for

LIVALO contains a medicine called pitavastatin. This belongs to a group of medicines called 'statins'. LIVALO is used to correct the levels of fat (lipid) in your blood and can be taken by children from the age of 6 years, as well as by adults. An imbalance of fats particularly cholesterol can sometimes lead to a heart attack or stroke.

You have been given LIVALO because you have an imbalance of fats and changing your diet and making lifestyle changes have not been enough to correct this. You should continue with your cholesterol-lowering diet and lifestyle changes while you are taking LIVALO.

How LIVALO works

LIVALO inhibits synthesis of cholesterol in the liver by its inhibitory effect on HMG-CoA reductase, and consequently lowers plasma cholesterol. LIVALO is usually used in the treatment of primary hyperlipidemia including familial hypercholesterolaemia or mixed dyslipidemia.

Before you use LIVALO

- When you must not use it

Do not take LIVALO:

- if you are allergic (hypersensitive) to pitavastatin, any other statin or the other ingredients of LIVALO (listed in '8. Product Description').
- if you are pregnant or breast-feeding.
- if you are a woman able to have children and you are not using a reliable contraceptive method (see 'Pregnancy, breast-feeding and fertility').
- if you currently have liver problems.
- if you take ciclosporin – used after an organ transplant.
- if you have repeated or unexplained muscle aches or pains.

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

- Pregnancy and breastfeeding

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

- Before you start to use it

Talk to your doctor or pharmacist before taking LIVALO if: you have severe respiratory failure (severe breathing problems). you have ever had problems with your kidneys.

- you have previously had liver problems. 'Statins' can affect the liver in a small number of people.

Your doctor will usually carry out a blood test (liver function test) before and during treatment with LIVALO.

- you have ever had problems with your thyroid gland.
- you or any member of your family have a history of muscle problems.
- you have had a previous history of muscle problems when taking other cholesterol-lowering medicines (e.g. statins or fibrates).
- you drink excessive amounts of alcohol.
- 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 LIVALO can lead to serious muscle problems (rhabdomyolysis).
- 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 'Side effects').

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

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.

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LIVALO 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. This includes any medicines obtained without a prescription and herbal remedies. Some medicines can stop each other from working properly. In particular tell your doctor or pharmacist if you are taking any of the following:

- other medicines called 'fibrates' - such as gemfibrozil and fenofibrate.
- erythromycin or rifampicin - types of antibiotics used for infections.
- warfarin or any other medicine used to thin the blood.
- medicines for HIV called 'protease inhibitors' (e.g. ritonavir, lopinavir, darunavir, atazanavir) and 'non-nucleoside reverse transcriptase inhibitors' (e.g. efavirenz).
- niacin (Vitamin B3).
- 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 LIVALO use. Taking LIVALO with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in 'Side effects'.

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

How to use LIVALO

- How much to use

Always take LIVALO exactly as your doctor has told you. Check with your

doctor or pharmacist if you are not sure.

The usual starting dose is 1mg or 2mg once a day. After a few weeks your doctor may decide to increase your dose. The maximum dose for adults and children over 10 is 4mg each day.

If you have problems with your liver you should not take more than 2mg a day.

- Use in children and adolescents

The maximum dose in children under 10 years is 2mg each day. If necessary, the tablets may be dispersed in a glass of water immediately before taking, then rinse the glass with a second volume of water and again drink immediately. Do not use fruit juices or milk to disperse the tablets. LIVALO is not recommended for use in children aged below 6 years.

- When to use it

Swallow the whole tablet, or half tablet of 2mg tablet (if 1mg is required) with a drink of water, with or without food. You can take it at any time of day. However, try to take your tablet at the same time every day.

- How long to use it

Do not stop taking LIVALO without talking to your doctor first. Your cholesterol levels might increase.

- 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 use too much (overdose)

If you take more LIVALO than you should, talk to a doctor or go to

hospital straight away. Take the medicine pack with you.

While you are using it

- Things you must do

- If you go into hospital or receive treatment for another problem, tell the medical staff that you are taking LIVALO.
- Your doctor may do regular cholesterol checks.

- Things you must not do

- Do not stop taking LIVALO without talking to your doctor first.

- Things to be careful of

Driving and using machines

- LIVALO is not expected to interfere with your ability to drive or operate machinery. However, if you feel dizzy or sleepy whilst taking LIVALO do not drive, use any machinery or tools.

Side effects

Like all medicines, LIVALO can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

- allergic reaction – the signs may include: difficulty breathing, swelling of the face, lips, tongue or throat, problems swallowing, severe itching of the skin (with raised lumps).
- unexplained muscle pain or weakness, especially if you feel unwell, have a fever or have reddish brown urine. LIVALO can rarely (less than 1 in 1,000 people) cause unpleasant muscle effects. If not

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- investigated they can lead to serious problems such as abnormal muscle breakdown (rhabdomyolysis), which can lead to kidney problems.
- breathing problems including persistent cough and/or shortness of breath or fever.
- liver problems which may cause yellowing of the skin and eyes (jaundice)
- pancreatitis (severe pain in the abdomen and back)

- Other side effects include:

- Common (affects less than 1 in 10 people):

- joint pain, muscle ache
- constipation, diarrhoea, indigestion, feeling sick
- headache.

- Uncommon (affects less than 1 in 100 people):

- muscle spasms
- feeling weak, weary or unwell
- swelling of the ankles, feet or fingers
- stomach pain, dry mouth, being sick, loss of appetite, altered taste
- pale skin and feeling weak or breathless (anaemia)
- itching or rash
- ringing in the ears
- feeling dizzy or sleepy, insomnia (other sleep disturbances including nightmares)
- increased need to go to the toilet (urinary frequency)
- feeling of numbness and reduced sensation in the fingers, toes, legs and face.

- Rare (affects less than 1 in 1,000 people):

- redness of the skin, raised red itchy skin
- deteriorating eye sight
- pain in the tongue
- unpleasant sensation or discomfort in the stomach

- Side effects of unknown frequency:

- Muscle weakness that is constant. If you have muscle problems that do not go away even after your doctor has told you to stop taking LIVALO, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

- 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.

- Other possible side effects:

- Memory loss
- Sexual difficulties
- Depression
- 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 may monitor you while you are taking this medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines AEFI))

Storage and Disposal of LIVALO

- Storage

Do not store above 30°C. To protect from light keep the blisters in the carton.

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 waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

LIVALO Film-coated Tablets are supplied in packs of 30. LIVALO Tablets 2mg is round, slightly light-colored yellow-red, scored film-coated tablets embossed

 and “202” on one face and scored on the reverse.

LIVALO Tablets 4mg is round, light yellow, scored film-coated tablets embossed  and “203” on one face and scored on the reverse.

- Ingredients

- Active ingredient
Pitavastatin calcium (as hydrate)
- Inactive ingredients
lactose hydrate, low substituted hydroxypropylcellulose, hypromellose, magnesium aluminometasilicate, magnesium stearate, triethyl citrate, hydrated silicon dioxide, titanium oxide, carnauba wax, food yellow No. 5 (sunset yellow FCF).

LIVALO Tablets 4 mg only contains yellow ferric oxide.

- MAL number:

Product Name: Registration Number

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MAL20046082AZ

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Manufacturer and Product

Registration Holder

- Manufactured by

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,

No. 1, Jalan SS 7/26A, Kelana Jaya,

47301 Petaling Jaya, Selangor,

Malaysia

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- 01/04/2024

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