



2mg and 4mg film-coated tablets  
Pitavastatin

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Livazo is and what it is used for
2. Before you take Livazo
3. How to take Livazo
4. Possible side effects
5. How to store Livazo
6. Further information

**1. WHAT LIVAZO IS AND WHAT IT IS USED FOR**

Livazo contains a medicine called pitavastatin. This belongs to a group of medicines called ‘statins’. Livazo is used to correct the levels of fat (lipid: cholesterol and triglycerides) in your blood. An imbalance of fats particularly cholesterol can sometimes lead to a heart attack or stroke. You have been given Livazo 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 Livazo.

**2. BEFORE YOU TAKE LIVAZO**

**Do not take Livazo if:**

- you are allergic (hypersensitive) to pitavastatin, any other statin or the other ingredients of Livazo (listed in “6. Further information”).
- you are pregnant or breast-feeding.
- you are a woman able to have children and you are not using a reliable contraceptive method (see “Pregnancy and breast-feeding”).
- you currently have liver problems.
- you take ciclosporin – used after an organ transplant.
- you have repeated or unexplained muscle aches or pains.

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

**Take special care with Livazo**

Check with your doctor or pharmacist before taking your medicine 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 Livazo.
- 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 large amounts of alcohol.

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

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently

taken, 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, fusidic acid or rifampicin - types of antibiotics used for infections.
- warfarin or any other medicine used to thin the blood.
- medicines for HIV called ‘protease inhibitors’ - such as atazanavir.
- niacin (vitamin B).

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

**Taking Livazo with food and drink**

Livazo can be taken with or without food.

**Pregnancy and breast-feeding**

Do not take Livazo if you are pregnant or breast-feeding. If you are trying to become pregnant, talk to your doctor.

If you are a woman who is able to have children, you must use a reliable contraceptive method, while taking Livazo. Stop taking Livazo and see a doctor straight away if you become pregnant while taking Livazo.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

**Driving and using machines**

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

**Important information about some of the ingredients of Livazo**

Livazo 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.

**3. HOW TO TAKE LIVAZO**

Always take Livazo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Taking this medicine**

Swallow the tablet whole with 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 much to take**

- The recommended dose is 2mg once a day. After a few weeks your doctor may decide to increase your dose. The maximum dose is 4mg each day.
- If you have problems with your liver you should not take more than 2mg a day.

**Children**

Livazo is not recommended for use in children aged below 18 years.

**Other things you need to know whilst taking Livazo**

- If you go into hospital or receive treatment for another problem, tell the medical staff that you are taking Livazo.
- Your doctor may do regular cholesterol checks.
- Do not stop taking Livazo without talking to your doctor first. Your cholesterol levels might increase.
- While you are on this medicine your doctor will monitor you closely if you have diabetes or 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, or if you are overweight and have high blood pressure.

**If you take more Livazo than you should**

If you take more Livazo than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you.

**If you forget to take a dose**

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

**4. POSSIBLE SIDE EFFECTS**

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

**Stop taking Livazo 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. Livazo can rarely (less than 1 in 1,000 people) cause unpleasant muscle effects. If not 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.

Most other side effects are usually mild and disappear after a short time, these 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)
- reduced sensation (hypoaesthesia)

**Rare (affects less than 1 in 1,000 people)**

- liver problems which may cause yellowing of the skin and eyes (jaundice)
- pancreatitis (severe pain in the abdomen and back)
- redness of the skin, raised red itchy skin
- deteriorating eye sight
- pain in the tongue
- Unpleasant sensation in the abdomen

**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, if you are overweight and have high blood pressure. Your doctor may monitor you while you are taking this medicine.

If any of the side effects becomes troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE LIVAZO**

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

Do not use Livazo after the expiry date stated on the carton and blister after EXP. The expiry date refers to the last day of that month. Keep your tablets in a safe place out of the reach and sight of children.

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

**6. FURTHER INFORMATION**

**What Livazo contains**

The active substance is pitavastatin. Each tablet contains 2.09 mg or 4.18 mg of pitavastatin calcium equivalent to 2 mg or 4 mg respectively of free base.

The other ingredients are: Lactose monohydrate, low substituted hydroxypropylcellulose, hypromellose (E464), magnesium aluminometasilicate, magnesium stearate, titanium dioxide (E171), triethyl citrate (E1505) and colloidal anhydrous silica.

**What Livazo looks like and contents of the pack**

Livazo tablets are round, white, biconvex film coated tablets engraved “ALG” on one side and “L2” or “L4” on the other.

Livazo is available in packs of 7, 28, 30 or 100 tablets.

Not all pack sizes may be marketed.

**For more information about this medicinal product, please contact:**

Algorithm SAL  
Tel: +961-9-222050

**To report any side effect:**

**Lebanon and all MENA countries**

Algorithm SAL  
Fax: +961-9-222141  
Email: pharmacovigilance@blgx.net  
Website : www.algorithm-lb.com

Also contact the relevant competent authority.

**This is a medicament**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Manufactured by  
**ALGORITHM S.A.L.**, Zouk Mosbeh, Lebanon  
Under license from  
Kowa Pharmaceutical Europe Co. Ltd., UK.  
® Registered Trademark

