

PACKAGE LEAFLET

Package leaflet: Information for the user**Alipza 1mg, 2mg and 4mg film-coated tablets**
pitavastatin

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.

What is in this leaflet:

1. What Alipza is and what it is used for
2. What you need to know before you take Alipza
3. How to take Alipza
4. Possible side effects
5. How to store Alipza
6. Contents of the pack and other information

1. What Alipza is and what it is used for

Alipza contains a medicine called pitavastatin. This belongs to a group of medicines called ‘statins’. Alipza 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 Alipza 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 Alipza.

2. What you need to know before you take Alipza**Do not take Alipza**

- if you are allergic (hypersensitive) to pitavastatin, any other statin or the other ingredients of this medicine (listed in section 6).
- 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 Alipza.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alipza 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 Alipza.
- 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 Alipza 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 section 4).

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

Children and adolescents

Alipza should not be given to children aged below 6 years.

Before taking Alipza adolescent girls should receive guidance and counselling on contraception.

Other medicines and Alipza

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 Alipza use. Taking Alipza with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- If you are taking medicines containing glecaprevir and pibrentasvir, medicines used to treat Hepatitis C. The doctor may need to change the dose of your Alipza.

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

Alipza with food and drink

Alipza can be taken with or without food.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

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

Alipza contains Lactose

Alipza contains lactose (a type of sugar). 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 Alipza

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

Taking this medicine

Swallow the tablet whole 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 much to take

- The usual starting dose is 1mg 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.
- Alipza is not recommended for use in children aged below 6 years.

Other things you need to know whilst taking Alipza

- If you go into hospital or receive treatment for another problem, tell the medical staff that you are taking Alipza.
- Your doctor may do regular cholesterol checks.
- Do not stop taking Alipza without talking to your doctor first. Your cholesterol levels might increase.

If you take more Alipza than you should

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

If you forget to take Alipza

Do not worry, just take your next dose at the correct time. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Stop taking Alipza 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. Alipza 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.
- 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.
- Breast enlargement in men (gynaecomastia).

Not known (frequency cannot be estimated from the available data)

- muscle weakness that is constant.
- lupus-like syndrome (including rash, joint disorders and effects on blood cells).
- 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.

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 MHRA yellow card scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alipza

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. The expiry date refers to the last day of the month.

Do not store above 25°C. Keep the blister in the outer carton in order to protect from light.

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 protect the environment.

6. Contents of the pack and other information**What Alipza contains**

- The active substance is pitavastatin calcium equal to 1mg, 2mg or 4mg of pitavastatin.
- The other ingredients are lactose monohydrate, LS-hydroxypropylcellulose, hypromellose (E464), titanium dioxide (E171), triethyl citrate (E1505), magnesium aluminometasilicate, magnesium stearate, colloidal anhydrous silica.

What Alipza looks like and contents of the pack

Alipza film-coated tablets are supplied in packs of 7, 28, 30, 90 or 100. Not all pack sizes may be marketed.

The tablets are round, white and marked on one side with the letters 'KC'. To help identify the different strengths, they are each a different size and marked with either '1', '2' or '4' on the other side.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Kowa Pharmaceutical Europe Co. Ltd.
105 Wharfedale Road, Wokingham,
RG41 5RB, United Kingdom.

Manufacturer: Pierre Fabre Médicament Production
Rue du Lycée, 45502 Gien Cedex, France

Or

Recodati Industria Chimica E Farmaceutica SpA
Via M Civitali 1, 20148, Milan, ITALY

This leaflet was last revised in []

Other sources of information

Detailed information on this medicine is available on the website of the MHRA www.mhra.gov.uk.

Note: Only the manufacture site responsible for product release into an individual market will be named on the leaflet circulated in that particular market.