

Package leaflet: Information for the user

Vaspit 1 mg filmomhulde tabletten
Vaspit 2 mg filmomhulde tabletten
Vaspit 4 mg filmomhulde tabletten
pitavastatine

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

1. What [Product name] is and what it is used for

[Product name] contains a medicine called pitavastatin. This belongs to a group of medicines called 'statins'. Pitavastatin 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 [Product name] 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 [Product name].

2. What you need to know before you take [Product name]

Do not take [Product name]

- if you are allergic to pitavastatin, any other statins or any of 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 [Product name].

Warnings and precautions

Talk to your doctor or pharmacist before taking [Product name]

- if you have severe respiratory failure (severe breathing problems).
- if you have ever had problems with your kidneys.

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

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

If 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).

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

[Product name] should not be given to children aged below 6 years.

Before taking [Product name] adolescent girls should receive guidance and counselling on contraception.

Other medicines and [Product name]

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 pitavastatin use. Taking pitavastatin 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 pitavastatin.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are trying to become pregnant, talk to your doctor before taking [Product name]. If you are a woman who is able to have children, you must use a reliable contraceptive method, while taking [Product name]. Stop taking [Product name] and see a doctor straight away if you become pregnant while taking [Product name]. Ask your doctor or pharmacist for advice before taking any medicine, if

you are pregnant or breast-feeding.

Driving and using machines

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

[Product name] contains 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 [Product name]

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 recommended starting dose is 1 mg 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 4 mg each day.

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

Use in children and adolescents

The maximum dose in children under 10 years is 2 mg 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.

[Product name] is not recommended for use in children aged below 6 years.

Other things you need to know whilst taking [Product name]

If you go into hospital or receive treatment for another problem, tell the medical staff that you are taking [Product name].

Your doctor may do regular cholesterol checks.

Do not stop taking [Product name] without talking to your doctor first. Your cholesterol levels might increase.

If you take more [Product name] than you should

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

If you forget to take [Product name]

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.

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

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 [Product name] 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. Pitavastatin 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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 label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the blister in the outer carton in order to protect from light.

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.

6. Contents of the pack and other information

What X contains

- The active substance is pitavastatin. Each film-coated tablet contains pitavastatin calcium equivalent to 1 mg, 2 mg or 4 mg pitavastatin.
- The other ingredients are: *tablet core*: lactose monohydrate, low substituted hydroxypropyl cellulose, magnesium aluminometasilicate, hypromellose 2910, magnesium stearate; *film coating*: Opadry white 03O580007 (hypromellose, titanium dioxide (E171), Triethyl citrate (E 1505), colloidal anhydrous silica), yellow iron oxide E172 (*2 mg tablets*).

What X looks like and contents of the pack

[Product name] 1 mg film-coated tablets: White round, concave, film coated tablets, debossed with '10' on one side and plain on the other side, with diameter approximately 6mm.

[Product name] 2 mg film-coated tablets: Yellow round, concave, film coated tablets, debossed with '20' on one side and plain on the other side, with diameter approximately 8mm.

[Product name] 4 mg film-coated tablets: White round, concave, film coated tablets, debossed with 'MC' on one side and plain on the other side, with diameter approximately 10.3mm.

Opaque blisters in cartons of 7, 28 or 30 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

Medochemie Limited
1-10 Constantinoupolis
3011 Limassol
Cyprus

Fabrikant:

Medochemie Limited
Factory Az
Agios Athanassios Industrial Area
Michali Irakleous 2
Agios Athanasios
4101 Limassol
Cyprus

In het register ingeschreven onder:

Vaspit 1 mg filmomhulde tabletten - RVG 129348
Vaspit 2 mg filmomhulde tabletten - RVG 129349
Vaspit 4 mg filmomhulde tabletten - RVG 129350

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland Vaspit 1 mg, 2 mg en 4 mg filmomhulde tabletten

Cyprus	Vaspit 1mg, 2mg and 4mg	Επικαλυμμένο με λεπτό υμένιο δισκίο
Griekenland	Vaspit 1mg, 2mg and 4mg	Επικαλυμμένο με λεπτό υμένιο δισκίο
Spanje	Vaspit 1mg, 2mg and 4mg	Comprimido recubierto con película
Malta	Vaspit 1mg, 2mg and 4mg	film-coated tablets

Deze bijsluiter is voor het laatst goedgekeurd in september 2023