

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ATORVASTATIN 10 VIATRIS tablets

ATORVASTATIN 20 VIATRIS tablets

ATORVASTATIN 40 VIATRIS tablets

ATORVASTATIN 80 VIATRIS tablets

Atorvastatin calcium

Contains sugar

Each ATORVASTATIN 10 VIATRIS tablet contains 32,80 mg lactose monohydrate

Each ATORVASTATIN 20 VIATRIS tablet contains 65,61 mg lactose monohydrate

Each ATORVASTATIN 40 VIATRIS tablet contains 131,22 mg lactose monohydrate

Each ATORVASTATIN 80 VIATRIS tablet contains 262,44 mg lactose monohydrate

Read all of this leaflet carefully before you start taking ATORVASTATIN VIATRIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ATORVASTATIN VIATRIS has been prescribed for you/your child personally and you/your child should not share your/his/her medicine with other people. It may harm them, even if their symptoms are the same as yours/theirs.

What is in this leaflet

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

1. What ATORVASTATIN VIATRIS is and what it is used for

ATORVASTATIN VIATRIS belongs to a group of medicines known as lipid or cholesterol (fat) regulating medicines commonly known as statins.

ATORVASTATIN VIATRIS lowers cholesterol in your/your child's blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your/your child's blood. It can raise your HDL-C ("good" cholesterol) as well. ATORVASTATIN VIATRIS is for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

ATORVASTATIN VIATRIS can lower risk of heart disease and disorders of the blood vessels of the brain, which are conditions due to reduced blood supply, in patients who have multiple risk factors for heart disease, such as smoking, hypertension, diabetes, low HDL-C, or a family history of early coronary heart disease. ATORVASTATIN VIATRIS can reduce heart events in patients with heart disease and high cholesterol levels.

2. What you need to know before you/your child take(s) ATORVASTATIN VIATRIS

Do not take/Your child should not take ATORVASTATIN VIATRIS

- If you/your child are/is hypersensitive (allergic) to atorvastatin or any of the other ingredients of ATORVASTATIN VIATRIS (listed in section 6).
- If you/your child are/is pregnant, trying to fall pregnant or breastfeeding.
- If you/your child are/is able to have children and are/is not using adequate contraceptive measures.
- If you/your child have/s or have/s had any liver disease or any unexplained abnormal blood tests for liver function.
- If you/your child use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.
- If you/your child are/is taking rifampicin, an antibiotic, for an infection.
- If you/your child are/is taking diltiazem, a calcium channel blocker, for angina or high blood pressure.
- If you/your child drink/s grapefruit juice.

Warnings and precautions

Take special care with ATORVASTATIN VIATRIS:

- If you/your child have/has a history of liver disease, serious liver injury or jaundice (yellow

discolouration of skin or whites of the eyes) or if you/your child drink/s excessive amounts of alcohol; your doctor may do blood tests to check your/your child's liver before you start taking ATORVASTATIN VIATRIS and if you have symptoms of liver problems while you take ATORVASTATIN VIATRIS.

- If you/your child have/has muscle disorders or if you/your child have/has had previous muscular problems during treatment with other lipid-lowering medicines e.g. other “statins” or “fibrate” medicines.
- If you/your child experience/s unexplained muscle pain, tenderness or weakness especially if accompanied by fever or a general feeling of being unwell during treatment with ATORVASTATIN VIATRIS; your doctor may need to carry out a blood test before and possibly during your ATORVASTATIN VIATRIS treatment to predict your risk of muscle-related side effects. 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/your child have/has a history of kidney problems as your doctor may need to monitor more closely for muscle-related side effects.
- If you/your child are/is taking any other medicines as the risk of muscle-related side effects may be increased if taken together with ATORVASTATIN VIATRIS (see section Other medicines and ATORVASTATIN VIATRIS).
- If you/your child are/is taking or have/has recently taken fusidic acid (used to treat bacterial infections) because the combination with ATORVASTATIN VIATRIS may lead to serious muscle problems; you may need to temporarily stop using ATORVASTATIN VIATRIS.
- If you/your child have/has ever had any type of stroke; your doctor will need to consider this in deciding the best treatment and dose for you.
- If you/your child have/has severe respiratory failure (difficulty breathing, non-productive cough with a general worsening of health including tiredness, weight loss and fever).
- If you/your child have/has diabetes or are at risk of developing diabetes as ATORVASTATIN VIATRIS can lead to high blood sugar. While you/your child are on this medicine, your doctor will monitor you closely. 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.

- If you/your child 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 you/your child have/has an underactive thyroid gland (hypothyroidism).

Other medicines and ATORVASTATIN VIATRIS

Always tell your/your child's health care provider if you/your child are/is taking any other medicine. (This includes all complementary or traditional medicines.)

There are some medicines that may change the effect of ATORVASTATIN VIATRIS, or their effect may be changed by ATORVASTATIN VIATRIS. This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including the important condition known as rhabdomyolysis (serious muscle pain and weakness often associated with fever). Your/your child's doctor will consider this in deciding upon your/your child's dose of ATORVASTATIN VIATRIS.

Some medicines that may interact with ATORVASTATIN VIATRIS include:

- Certain antibiotics or antifungal medicines e.g. erythromycin, clarithromycin, clotrimazole, rifampicin and itraconazole.
- Medicines used to treat HIV e.g. saquinavir, lopinavir, the combination tipranavir/ritonavir, darunavir, fosamprenavir, nelfinavir and efavirenz.
- Some calcium channel blockers used for angina or high blood pressure e.g. diltiazem.
- Medicines used to modulate immune response e.g. ciclosporin.
- Medicines used to treat hepatitis C e.g. telaprevir, boceprevir, glecaprevir, pibrentasvir, elbasvir, grazoprevir, simeprevir and ledipasvir/sofosbuvir.
- Letermovir (antiviral medicine for cytomegalovirus infections).
- Antacids (indigestion products containing aluminium or magnesium).
- Other medicines to regulate lipid (fat) levels e.g. gemfibrozil, fenofibrate, fibric acid derivatives, colestipol, niacin (nicotinic acid or vitamin B3).
- Medicines to regulate your/your child's heart rhythm e.g. digoxin.
- Oral contraceptives.

- Warfarin and ticagrelor (which reduce blood clotting).
- Colchicine (used to treat gout, a kind of arthritis).
- Fusidic acid (used to treat bacterial infections). If you need to take fusidic acid orally or by injection 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 ATORVASTATIN VIATRIS. Taking ATORVASTATIN VIATRIS with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). Tell your doctor if you are taking or have taken fusidic acid orally or by injection in the last 7 days.
- Medicines obtained without a prescription: St. John's Wort.
- Daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteria present in the blood).

ATORVASTATIN VIATRIS with food and drink

Grapefruit juice should be avoided when taking ATORVASTATIN VIATRIS as this combination can result in an undesirable interaction.

ATORVASTATIN VIATRIS can be taken with or without food.

Pregnancy and breastfeeding

Do not take/Your child should not take ATORVASTATIN VIATRIS:

- If you/your child are/is pregnant, trying to fall pregnant or breastfeeding.
- If you/your child are/is able to have children and are/is not using adequate contraceptive measures.

An interval of one month should be allowed from stopping ATORVASTATIN VIATRIS treatment to conception in the event of planning a pregnancy.

If you/your child are/is pregnant or breastfeeding, think you/she may be pregnant or are/is planning to have a baby, please consult your/your child's doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent ATORVASTATIN VIATRIS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ATORVASTATIN VIATRIS affects them.

ATORVASTATIN VIATRIS contains lactose

ATORVASTATIN VIATRIS contains lactose. If you/your child have/has been told by your doctor that

you/your child have/has an intolerance to some sugars, contact your/your child's doctor before taking this medicine.

3. How to take ATORVASTATIN VIATRIS

Do not/your child should not share medicines prescribed for you/him/her with any other person.

Always take ATORVASTATIN VIATRIS exactly as your/your child's doctor has told you. Check with your/your child's doctor or pharmacist if you are not sure.

The usual starting dose is 10 mg once a day in adults and children aged 10 years or older. Your/your child's doctor may increase the dose, if necessary until you/your child are/is taking the correct amount required. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose is 80 mg once a day.

ATORVASTATIN VIATRIS tablets can be taken all at once, at any time of the day with or without food.

However, try to take your tablet at the same time every day. Remember to continue with your/your child's diet and lifestyle changes while you/your child are/is taking ATORVASTATIN VIATRIS.

Your/your child's doctor will tell you how long your/your child's treatment with ATORVASTATIN VIATRIS will last. If you have the impression that the effect of ATORVASTATIN VIATRIS is too strong or too weak, tell your/your child's doctor or pharmacist.

If you/your child take/s more ATORVASTATIN VIATRIS than you/he/she should

In the event of overdosage, consult your/your child's doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you/your child forget/s to take ATORVASTATIN VIATRIS

If you/your child miss/es a dose of ATORVASTATIN VIATRIS, take/your child should take it as soon as you/he/she remember/s, unless it is time to take the next dose. Do not/your child should not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ATORVASTATIN VIATRIS can have side effects.

Not all side effects reported for ATORVASTATIN VIATRIS are included in this leaflet. Should your/your child's general health worsen or if you/your child experience/s any untoward effects while taking

ATORVASTATIN VIATRIS, please consult your health care provider for advice.

If any of the following happens, stop/your child should stop taking/using ATORVASTATIN VIATRIS and tell your/your child's doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing.
- Allergic skin reactions including widespread rash, redness, blistering, pustules or peeling of large areas of skin that may be combined with fever, feeling unwell, or swelling of the mouth, nose, eyes, genitals or lymph nodes.

These are all very serious side effects. If you/your child have/has them, you/your child may have had a serious reaction to ATORVASTATIN VIATRIS. You/your child may need urgent medical attention or hospitalisation.

Tell your/your child's doctor immediately or go/take your child to the casualty department at your nearest hospital if you notice any of the following:

Liver problems:

Symptoms of liver problems include:

- Feeling more tired or weak than usual.
- Loss of appetite.
- Upper belly or stomach pain.
- Passing brown or dark, amber-coloured urine.
- Yellowing of your/your child's skin or the whites of your eyes.
- Nausea and vomiting.

Muscle problems:

- ATORVASTATIN VIATRIS can cause serious muscle problems that can lead to kidney problems, including kidney failure. You/your child have/has a higher risk for muscle problems if you/your child are/is taking certain other medicines with ATORVASTATIN VIATRIS (see Other medicines and ATORVASTATIN VIATRIS).
- Muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you/your child also have/has a fever or feel/s more tired than usual. This may be an early sign of a rare muscle problem.

- Muscle problems that do not go away even after your/your child's doctor has advised you/your child to stop taking ATORVASTATIN VIATRIS. Your/your child's doctor may do further tests to diagnose the cause of your/your child's muscle problems.

These are all serious side effects. You/your child may need urgent medical attention.

Side effects reported in clinical trials include the following:

Infection, flu-like syndrome, allergic reaction, headache, sinusitis, pharyngitis, stomach pain, constipation, diarrhoea, dyspepsia, flatulence, rash, back pain, joint pain, muscle pain, weakness, accidental injury.

Tell your/your child's doctor if you notice any of the following:

Frequent side effects:

- Inflammation of the nasal passages.
- High blood sugar.
- Inability to sleep.
- Reduced sensitivity to touch.
- Tingling.
- Dizziness.
- Headache.
- Throat pain.
- Nose bleeds.
- Nausea.
- Diarrhoea.
- Stomach pain.
- Indigestion.
- Constipation.
- Flatulence (wind).
- Itching.
- Rash.
- Muscle pain.
- Pain in joints.

- Pain in arms and legs.
- Muscle spasms.
- Joint swelling.
- Back pain.
- Weakness.
- Chest pain.
- Abnormal blood test for liver function.
- Abnormal blood test showing muscle damage.

Less frequent side effects:

- Too few blood platelets.
- Low blood sugar.
- Anorexia (loss of appetite).
- Weight gain.
- Nightmares.
- Nerve disease affecting the extremities of the body.
- Loss of memory.
- Change in sense of taste.
- Blurred vision.
- Ringing in the ears.
- Purple skin lesions (signs of blood vessel inflammation, vasculitis).
- Belching (burping).
- Inflammation of the pancreas.
- Inflammation of the liver.
- Decreased bile flow (causing yellowing of skin and eyes, itching and dark, amber-coloured urine).
- Loss of hair.
- Rash that may occur on the skin or sores in the mouth (lichenoid drug reaction).
- Neck pain.
- Muscle cramps.
- Impotence.

- Feeling unwell.
- Fever.
- Positive urine test for white blood cells.
- Tendon injury.

Frequency not known:

- 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 side effects include:

- Cognitive impairment (e.g. memory loss, forgetfulness, memory impairment and confusion).

Possible side effects reported with some statins (medicines of the same type):

- Depression.

If you/your child notice/s any side effects not mentioned in this leaflet, please inform your/your child's doctor or pharmacist.

Reporting of side effects

If you/your child get/s side effects, talk to your/your child's doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ATORVASTATIN VIATRIS.

5. How to store ATORVASTATIN VIATRIS

- Store all medicines out of reach of children.
- Store at or below 30 °C in a dry place.
- Store in the original package.
- Keep the blister in the outer carton.
- Protect from light and moisture.
- Do not store in bathroom.

- Do not use after the expiry date stated on the blister/ carton
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ATORVASTATIN VIATRIS contains

- The active substance is atorvastatin calcium trihydrate. Each ATORVASTATIN VIATRIS tablet contains atorvastatin calcium trihydrate equivalent to 10/20/40/80 mg atorvastatin, respectively.
- The other ingredients in the tablets are calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.
- The other ingredients in the coating of ATORVASTATIN VIATRIS tablets are Opadry white (consisting of hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide and talc) and simethicone emulsion (consisting of simethicone, stearate emulsifiers, thickeners, benzoic acid and sorbic acid). The 10, 20 and 40 mg tablets also contain candelilla wax.

What ATORVASTATIN VIATRIS looks like and contents of the pack

ATORVASTATIN 10 VIATRIS: A white, elliptical, film-coated tablet, debossed with '10' on one side and 'VLE 155' on the other side.

ATORVASTATIN 20 VIATRIS: A white, elliptical, film-coated tablet, debossed with '20' on one side and 'VLE 156' on the other side.

ATORVASTATIN 40 VIATRIS: A white, elliptical, film-coated tablet, debossed with '40' on one side and 'VLE 157' on the other side.

ATORVASTATIN 80 VIATRIS: A white, elliptical, film-coated tablet, debossed with '80' on one side and 'VLE 158' on the other side.

ATORVASTATIN VIATRIS tablets are available in polyamide-aluminium-PVC/aluminium foil blister packs of 28, 30, 56, 60, 84, 90, 100 and 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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