

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ASPAVOR® 10 Tablet

ASPAVOR® 20 Tablet

ASPAVOR® 40 Tablet

ASPAVOR® 80 Tablet

Atorvastatin

Read this leaflet carefully before you start using ASPAVOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- ASPAVOR has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ASPAVOR CONTAINS:

Each ASPAVOR tablet contains the active ingredient atorvastatin calcium trihydrate, equivalent to 10/20/40/80 mg atorvastatin respectively.

ASPAVOR tablets contain the following inactive ingredients: Calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.

The coating of ASPAVOR tablets contains 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 ASPAVOR IS USED FOR:

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

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

ASPAVOR 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. ASPAVOR can prevent heart events in patients with heart disease or high cholesterol levels.

BEFORE TAKING ASPAVOR:

Do not take ASPAVOR if:

- You are allergic to any of the ingredients of ASPAVOR.
- You are pregnant, trying to fall pregnant or breastfeeding.
- You are able to have children and are not using adequate contraceptive measures.
- You have or have had any liver disease or any unexplained abnormal blood tests for liver function.
- You are taking rifampicin, an antibiotic, for an infection.
- You are taking diltiazem, a calcium channel blocker, for angina or high blood pressure.
- You drink grapefruit juice.

Take special care with ASPAVOR if:

Tell your doctor if:

- You have kidney problems.
- You have an underactive thyroid gland (hypothyroidism).
- You have muscle disorders or if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other "statins" or "fibrate" medicines).
- You drink excessive amounts of alcohol and/or have a history of liver disease.
- You have an intolerance to some sugars.
- You are taking any of the following medication as the risk of muscle-related side effects are increased if taken together with ASPAVOR:

- Colchicine (used to treat gout, a kind of arthritis).
 - Vitamin B3.
 - Fibric acid derivatives (a class of medicines also used to lower blood fat levels).
 - Telaprevir and boceprevir (used to treat hepatitis C).
 - Saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, atazanavir plus ritonavir and fosamprenavir plus ritonavir (combination of protease inhibitors used to treat HIV).
 - Immunosuppressive medicines (medicines that inhibit or prevent activity of the immune system).
 - Azole antifungal medication (used to treat fungal infections).
 - Fusidic acid or erythromycin (antibiotics used to treat bacterial infections).
- You have diabetes as ASPAVOR can lead to high blood sugar.

Tell your doctor if you have ever had any type of stroke; your doctor will need to consider this in deciding the best treatment and dose for you.

Tell your doctor if serious liver injury or jaundice (yellow discolouration of skin or whites of the eyes) occurs.

If you experience unexplained muscle pain, tenderness or weakness especially if accompanied by fever or a general feeling of being unwell, tell your doctor. Your doctor may need to carry out a blood test before and possibly during your ASPAVOR treatment to predict your risk of muscle-related side effects.

Taking ASPAVOR with food and drink:

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

Pregnancy and breastfeeding:

Do not take ASPAVOR if:

- You are pregnant, trying to fall pregnant or breastfeeding.
- You are able to have children and are not using adequate contraceptive measures.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking ASPAVOR.

Important information about some of the ingredients of ASPAVOR:

ASPAVOR contains lactose. You should not take ASPAVOR and should contact your doctor if you have rare hereditary problems, or a history of lactose or galactose intolerance (the body is unable to absorb certain sugars), Lapp lactase deficiency (the body is unable to digest milk and milk products due to lack of an enzyme) or glucose-galactose malabsorption (the body is unable to absorb certain sugars).

Taking other medicines with ASPAVOR:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ASPAVOR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

There are some medicines that may change the effect of ASPAVOR, or their effect may be changed by ASPAVOR. 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 doctor will consider this in deciding upon your dose of ASPAVOR.

Some medicines that may interact with ASPAVOR include:

- Medicines used to modulate immune response e.g. ciclosporin.
- Certain antibiotics or antifungal medicines e.g. erythromycin, clarithromycin, clotrimazole, rifampicin and itraconazole.
- Other medicines to regulate lipid (fat) levels e.g. fibric acid derivatives, colestipol, niacin (nicotinic acid).
- Some calcium channel blockers used for angina or high blood pressure e.g. diltiazem.
- Medicines to regulate your heart rhythm e.g. digoxin.
- Protease inhibitors used in the treatment of HIV e.g. nelfinavir, saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir and atazanavir plus ritonavir.
- Efavirenz used in the treatment of HIV.
- Other medicines known to interact with ASPAVOR include warfarin (which reduces blood clotting), oral contraceptives, antacids (indigestion products containing aluminium or magnesium) and fusidic acid.
- Telaprevir and boceprevir (used to treat hepatitis C).

- Colchicine (used to treat gout, a kind of arthritis).

HOW TO TAKE ASPAVOR:

Do not share ASPAVOR that is prescribed for you with any other person.

Always take ASPAVOR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting dose is 10 mg once a day. Your doctor may increase the dose, if necessary until you are taking the correct amount required. The maximum dose is 80 mg once a day. ASPAVOR tablets can be taken 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 diet and lifestyle changes while you are taking ASPAVOR.

If you forget to take ASPAVOR:

If you miss a dose of ASPAVOR, take it as soon as you remember unless it is time to take the next dose. Do not take 2 doses at the same time.

If you take more ASPAVOR than you should:

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

POSSIBLE SIDE EFFECTS:

ASPAVOR can have side effects. Not all side effects reported for ASPAVOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPAVOR, please consult your doctor, pharmacist or other health care professional for advice.

Serious side effects include:

- **Muscle problems**

ASPAVOR can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with ASPAVOR (see Taking other medicines with ASPAVOR).

- **Liver problems**

Your doctor may do blood tests to check your liver before you start taking ASPAVOR and if you

have symptoms of liver problems while you take ASPAVOR. Symptoms of liver problems include:

- Feeling tired or weak.
- Loss of appetite.
- Upper belly pain.
- Dark amber-coloured urine.
- Yellowing of your skin or the whites of your eyes.

Call your doctor immediately if you have:

- Muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual. This may be an early sign of a muscle problem.
- Muscle problems that do not go away even after your doctor has advised you to stop taking ASPAVOR. Your doctor may do further tests to diagnose the cause of your muscle problems.
- Allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- Nausea and vomiting.
- Passing brown or dark-coloured urine.
- Loss of appetite.
- You feel more tired than usual.
- Your skin and whites of your eyes get yellow.
- Stomach pain.
- Allergic skin reactions.

Other side effects include:

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

Other frequent side effects which have been reported include the following:

Diarrhoea, constipation, wind, indigestion, headache, pain in joints, chest pain, inability to sleep, back pain, numbness, tingling, reduced sensitivity to touch, dizziness and itching.

Other less frequent side effects which have been reported are:

Ringings in the ears, feeling unwell, loss of memory, impotence, loss of hair, and change in sense of taste, inflammation of the pancreas, inflammation of the liver, too few blood platelets, tendon problems,

low blood sugar, high blood sugar, anorexia (eating disorder), weight gain, nerve disease affecting the extremities of the body, change in sense of taste, swelling of hands and feet and muscle cramps.

Additional side effects reported after the marketing of ASPAVOR include:

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

Should any of these symptoms occur or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist immediately.

STORING AND DISPOSING OF ASPAVOR:

Store all medicines out the reach of children.

Store at or below 30 °C in a dry place.

Do not take ASPAVOR after the expiry date shown on the blister label. If your tablets are out of date, take them to your pharmacist who will get rid of them safely.

PRESENTATION OF ASPAVOR:

ASPAVOR tablets are available in silver coloured aluminium foil blister packed in cardboard cartons with a package insert containing 28, 30, 56, 60, 84, 90, 100 or 500 tablets.

IDENTIFICATION OF ASPAVOR:

ASPAVOR 10: White, oval film-coated tablet stamped with '10' on one side and 'PD 155' on the other.

ASPAVOR 20: White, oval film-coated tablet stamped with '20' on one side and 'PD 156' on the other.

ASPAVOR 40: White, oval film-coated tablet stamped with '40' on one side and 'PD 157' on the other.

ASPAVOR 80: White, oval film-coated tablet stamped with '80' on one side and 'PD 158' on the other.

REGISTRATION NUMBERS:

ASPAVOR 10: A39/7.5/0017

ASPAVOR 20: A39/7.5/0018

ASPAVOR 40: A39/7.5/0019

ASPAVOR 80: 43/7.5/0837

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Manufacturer: Pfizer Pharmaceuticals, LLC, Vega Baja, Puerto Rico

DATE OF PUBLICATION:

22 April 2016

BOTSWANA: S2

ASPAVOR 10 – Reg. No. BOT1101986

ASPAVOR 20 – Reg. No. BOT1101987

ASPAVOR 40 – Reg. No. BOT1101988

NAMIBIA: NS2

ASPAVOR 10 – Reg. No. 07/7.5/0125

ASPAVOR 20 – Reg. No. 07/7.5/0124

ASPAVOR 40 – Reg. No. 07/7.5/0123

ZAMBIA: POM

ASPAVOR 10 – Reg. No. 357/001

ASPAVOR 20 – Reg. No. 357/002

ASPAVOR 40 – Reg. No. 357/003

ZIMBABWE: PP

ASPAVOR 10 – Reg. No. 2012/12.8/4722

ASPAVOR 20 – Reg. No. 2012/12.8/4723

ASPAVOR 40 – Reg. No. 2012/12.8/4724