

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN PRAVASTATIN 10 mg tablets

Pravastatin sodium

Contains sugar: Lactose monohydrate 51,25 mg

ASPEN PRAVASTATIN 20 mg tablets

Pravastatin sodium

Contains sugar: Lactose monohydrate 102,50 mg

ASPEN PRAVASTATIN 40 mg tablets

Pravastatin sodium

Contains sugar: Lactose monohydrate 205 mg

Read all of this leaflet carefully before you start taking ASPEN PRAVASTATIN

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

What is in this leaflet

1. What ASPEN PRAVASTATIN is and what it is used for
2. What you need to know before you take ASPEN PRAVASTATIN

3. How to take ASPEN PRAVASTATIN
4. Possible side effects
5. How to store ASPEN PRAVASTATIN
6. Contents of the pack and other information

1. What ASPEN PRAVASTATIN is and what it is used for

The active ingredient in ASPEN PRAVASTATIN is pravastatin.

This belongs to a group of medicines called statins or HMG-CoA reductase inhibitors. These work by reducing the amount of cholesterol and other fatty substances called triglycerides in your blood. Nearly all of this cholesterol is made by your liver. Your body produces most of this cholesterol at night. For this reason, it is recommended that you take your ASPEN PRAVASTATIN tablet in the evening or at night.

Your doctor has prescribed ASPEN PRAVASTATIN tablets for you to reduce the cholesterol and other fatty substances in your blood and to reduce the health risks linked with coronary heart disease (CHD). If you have or are at risk of developing CHD, these tablets may help to keep your arteries clear.

2. What you need to know before you take ASPEN PRAVASTATIN

Do not take ASPEN PRAVASTATIN:

- If you are hypersensitive (allergic) to pravastatin sodium or any of the other ingredients of ASPEN PRAVASTATIN (listed in section 6),
- if you have acute or chronic liver disease,
- if you are pregnant or breastfeeding your baby,
- if you have a history of unexplained persistent increased blood levels of liver enzymes, called serum transaminases,

- If you have porphyria.

Warnings and precautions

Special care should be taken with ASPEN PRAVASTATIN:

- If you have a rare condition marked by increased levels of high density lipoprotein cholesterol (HDL-C),
- if you regularly drink large amounts of alcohol,
- if you have liver disease,
- if you have any diseases of skeletal muscles or muscle tissue, or if you have muscle pain, tenderness or weakness of your muscles. Please consult your doctor. He/she will decide whether you should keep taking your tablets or not,
- if you have kidney problems,
- if you are taking ciclosporin (an immunosuppressant drug) at the same time as ASPEN PRAVASTATIN, your doctor will advise you to stop taking ASPEN PRAVASTATIN,
- if you have suffered from any of these problems: renal impairment, hypothyroidism, a history of muscle disorder in yourself or a blood relative or alcohol abuse,
- if you are older than 70 years, your doctor will need to carry out a blood test before and possibly during your treatment. These blood tests will be used to evaluate your risk of muscle-related side effects.
- if you have a risk for diabetes (high blood sugar), please inform your doctor.

If you have any of the following symptoms: non-productive (dry) cough and deterioration of general health (tiredness, weight loss and fever), please consult your doctor.

Children

Use in paediatric patients is not recommended, as safety and efficacy have not been established.

Other medicines and ASPEN PRAVASTATIN

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Cyclosporin (used to suppress the immune system).
- Itraconazole, ketoconazole (medicines used to treat fungal infections).
- Erythromycin, clarithromycin, fusidic acid (antibiotics for treating infections).
- HIV-protease inhibitors (such as telaprevir, darunavir, ritonavir etc.).
- Nefazodone (medicine used to treat depression).
- Gemfibrozil or other fibrates (medicines used to treat hypercholesterolaemia).
- Niacin (a vitamin B supplement)
- Cholestyramine or colestipol (medicines used to lower the levels of cholesterol in the blood)
- Colchicine (used in the treatment of gout).
- Rifampicin (medicine used in the treatment of tuberculosis (TB))
- Lenalidomide (medicine used in treatment of plasma cell cancer)
- Digoxin (medicine used in the treatment of various heart conditions).
- Warfarin or other anticoagulants (medicine used to prevent blood clots).

ASPEN PRAVASTATIN with food

ASPEN PRAVASTATIN can be taken with meals or on an empty stomach.

Pregnancy, breastfeeding and fertility

You should not take ASPEN PRAVASTATIN if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

ASPEN PRAVASTATIN tablets may affect your ability to drive. When driving vehicles or operating machines, it should be considered that dizziness and visual disturbances may occur during treatment.

It is not always possible to predict to what extent ASPEN PRAVASTATIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN PRAVASTATIN affects you (see section 4).

ASPEN PRAVASTATIN contains lactose monohydrate

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 ASPEN PRAVASTATIN

Do not share medicines prescribed for you with any other person.

Always take ASPEN PRAVASTATIN exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

ASPEN PRAVASTATIN must be taken in combination with a low fat diet.

ASPEN PRAVASTATIN can be taken with meals or on an empty stomach.

The usual starting dose for hypercholesterolaemia is 10 mg as a single dose in the evening.

The usual starting dose for coronary heart disease is 20 mg as a single dose in the evening. Your doctor may adjust your dose to a maximum of 80 mg a day, as a single dose, taken in the evening (this 80 mg dose is recommended only for patients with a severely high level of cholesterol in their blood).

Your doctor may prescribe lower doses, particularly if you are taking some of the medicines listed above or have certain kidney conditions. Your doctor may have to change the dosage in order to achieve the best effect.

Your doctor will tell you how long your treatment with ASPEN PRAVASTATIN will last. Do not stop treatment early than what the doctor has instructed you. If you have the impression that the effect of ASPEN PRAVASTATIN is too strong or too weak, tell your doctor or pharmacist.

If you take more ASPEN PRAVASTATIN 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.

If you forget to take ASPEN PRAVASTATIN

Do not take a double dose to make up for forgotten individual doses. If you miss a dose of ASPEN PRAVASTATIN, take it as soon as you remember. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

ASPEN PRAVASTATIN can have side effects.

Not all side effects reported for ASPEN PRAVASTATIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN PRAVASTATIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking ASPEN PRAVASTATIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- toxic epidermal necrolysis.

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN PRAVASTATIN. You may need urgent medical attention or hospitalisation.

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

- Hepatitis, liver failure (symptoms include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-coloured stools, joint pain, and jaundice),
- a deficiency of red blood cells, low white blood cell count,
- inflammation of the pancreas; usually marked by abdominal pain, nausea, vomiting or rapid pulse,
- muscle damage, muscle aches and pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage,
- ocular myasthenia usually marked by double vision (seeing two images instead of one), trouble focusing, and drooping eyelids which could intensify to myasthenia gravis affecting the muscles throughout the body,
- drooping of one or both eyelids (ptosis), weakness in the arms, hands, fingers, legs, and neck (these are symptoms of myasthenia gravis),

- interstitial lung disease usually marked by shortness of breath.

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

Tell your doctor if you notice any of the following:

- Dizziness and headache,
- weakness, numbness and pain in hands and feet (peripheral neuropathy),
- abnormal sensation, typically tingling or pricking (paraesthesia),
- loss of hair (alopecia),
- physical weakness or lack of energy (fatigue).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, dizziness, abnormal sensation of the skin (paraesthesia),
- skin rash, hair loss (alopecia),
- muscle pains, muscle cramps,
- fatigue.

Less frequent side effects:

- Constipation, diarrhoea, nausea, vomiting, flatulence, indigestion (dyspepsia), abdominal pain, cramps,
- abnormal urination (including dysuria, frequency, nocturia),
- sexual impotence in men.

Side effects with an unknown frequency:

- High blood sugar (hyperglycaemia),
- weight gain,
- trouble sleeping,

- inflammation of blood vessels (vasculitis).

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

Reporting of side effects

If you get side effects, talk to your 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.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of ASPEN PRAVASTATIN.

5. How to store ASPEN PRAVASTATIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ASPEN PRAVASTATIN contains

ASPEN PRAVASTATIN 10 mg tablet

The active substance is 10 mg pravastatin sodium

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium aluminium silicate, magnesium stearate, microcrystalline cellulose, povidone, talc.

Contains sugar: Lactose monohydrate 51,25 mg

ASPEN PRAVASTATIN 20 mg tablet

The active substance is 20 mg pravastatin sodium

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium aluminium silicate, magnesium stearate, microcrystalline cellulose, povidone, talc.

Contains sugar: Lactose monohydrate 102,50 mg

ASPEN PRAVASTATIN 40 mg tablet

The active substance is 40 mg pravastatin sodium

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium aluminium silicate, magnesium stearate, microcrystalline cellulose, povidone, talc.

Contains sugar: Lactose monohydrate 205 mg.

What ASPEN PRAVASTATIN looks like and contents of the pack

ASPEN PRAVASTATIN 10 mg is a white to off-white, capsule shaped, biconvex tablet with "PR10" on one side.

30 tablets are packed in foil on foil blister strips consisting of an aluminium foil lined with polyvinyl chloride/polyamide/aluminium on the top and backed with plain aluminium foil.



There are 10 tablets per blister strip and 3 blister strips are packed into an outer cardboard carton together with a leaflet.

ASPEN PRAVASTATIN 20 mg is a white to off-white, capsule shaped, biconvex tablet with "PR20" on one side.

30 tablets are packed in foil on foil blister strips consisting of an aluminium foil lined with polyvinyl chloride/polyamide/aluminium on the top and backed with plain aluminium foil.

There are 10 tablets per blister strip and 3 blister strips are packed into an outer cardboard carton together with a leaflet.

ASPEN PRAVASTATIN 40 mg is a white to off-white, capsule shaped, biconvex tablet with "PR40" on one side.

30 tablets are packed in foil on foil blister strips consisting of an aluminium foil lined with polyvinyl chloride/polyamide/aluminium on the top and backed with plain aluminium foil.

There are 6 tablets per blister strip and 5 blister strips are packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200



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Registration numbers

ASPEN PRAVASTATIN 10 mg: 38/7.5/0123

ASPEN PRAVASTATIN 20 mg: 38/7.5/0139

ASPEN PRAVASTATIN 40 mg: 38/7.5/0140

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS2
10 mg 05/7.1/0493
20 mg 05/7.1/0491
40 mg 05/7.1/0489

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