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PACKAGE LEAFLET: INFORMATION FOR THE USER

PRAVASTATIN SODIUM 10 mg TABLETS PRAVASTATIN SODIUM 20 mg TABLETS PRAVASTATIN SODIUM 40 mg TABLETS

Pravastatin Sodium

Read all of this leaflet carefully before you start taking this medicine
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pravastatin Sodium Tablets is and what it is used for

Pravastatin Sodium Tablets belongs to a group of medicines called statins (or HMG-CoA reductase inhibitors). It prevents the production of cholesterol by the liver and consequently reduces the levels of cholesterol and other fats (triglycerides) in your body. When there are excessive levels of cholesterol in the blood, the cholesterol accumulates on the walls of blood vessels and block them. This condition is called hardening of the arteries or atherosclerosis, may lead to:
- chest pain (angina pectoris), when a blood vessels in the heart is partially blocked,
- a heart attack (myocardial infraction), when a blood vessels in the heart is completely blocked,
- a stroke (cerebrovascular accident), when a blood vessel in the brain is completely blocked.

This medicine is used in 3 situations:
In the treatment of high levels of cholesterol and fats in the blood Pravastatin Sodium Tablets is used to lower high levels of "bad" cholesterol and to raise the levels of "good" cholesterol in the blood when changes to diet and exercise have failed to adequately do this.

In the prevention of heart and blood vessel diseases
- If you have high levels of cholesterol in your blood and risk factors favouring these diseases (if you smoke, are overweight, if you have high blood sugar levels or high blood pressure, if you take little exercise), Pravastatin Sodium Tablets is used to reduce the risk of you having heart and blood vessel diseases and to lower your risk of dying from these diseases.
- If you have already had a heart attack or have unstable angina (chest pain) and you have normal cholesterol levels, Pravastatin Sodium reduces the risk of you having another heart attack or stroke in the future.-

After organ transplants:
If you have had an organ transplant and are taking medication to stop your body rejecting the transplant, Pravastatin Sodium reduces increased lipid levels.

2. Before you take Pravastatin Sodium Tablets

Do not take Pravastatin Sodium Tablets in following conditions:
- if you have a liver disease.(active liver diseases);
- if you are hypersensitive (allergic) to Pravastatin Sodium or any of the other ingredients of this medicine(see further information);
- if you are pregnant, trying to become pregnant or if you are breast-feeding (see Pregnancy and breast -freeding);
- if several blood tests have shown abnormal functioning of your liver (increased levels of liver enzymes in the blood).

Warnings and precautions
Talk to your doctor ,pharmacist or nurse before taking Pravastatin Sodium Tablets :
- If you have kidney disease.
- If you have an underactive thyroid (hypothyroidism);
- If you have past history of liver disease.
- If you have alcohol problems (If you regularly drink large amounts of alcohol).
- If you have a hereditary muscle disorder in yourself or a blood relative.
- If you have side effects affecting your muscles when taking another cholesterol-lowering medicine such as statin or fibrate.
- If you have experienced 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 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 Pravastatin Sodium can lead to serious muscle problems (rhabdomyolysis).

If you have suffered any of these problems, your doctor will need to carry out a blood test before and possibly during Pravastatin Sodium treatment to assess your risk of muscle-related side effects. You may also need this blood test if you are aged older than 70 years. If you feel any unexplained cramps or muscle pains during treatment, tell your doctor immediately.

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.

Check with your doctor or pharmacist before taking Pravastatin sodium Tablets if you:
- Have severe respiratory failure

Using other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines before you start to take Pravastatin Sodium Tablets as the combination may result in an increased risk of developing muscle problems.
- A group of cholesterol lowering drugs called fibrates (e.g. gemfibrozil, fenofibrate) or nicotinic acid.
- The immunosuppressant ciclosporin.
- The antibiotics such as erythromycin or clarithyromycin treats the infection caused by bacteria.
- another medicine which lowers the level of cholesterol in your blood (nicotinic acid).
- A resin type lipid-lowering agent such as colestyramine or colestipol, Pravastatin Sodium Tablets should be taken atleast one hour before or four hours after you have taken the resin. This is because the resin can affect the absorption of Pravastatin Sodium if the two medicines are taken too closely together.
- Warfarin and other oral anticoagulants (agents that help in thinning the blood).
- Product metabolized by cytochrome P450 (diltiazem, verapamil, itraconazole, ketoconazole, protease inhibitors and CYP2C9 inhibitors like fluconazole).
- If you are taking a drug used to treat and prevent formation of blood clots called “vitamine K antagonist”, tell your doctor before taking Pravastatin Sodium because the use of vitamin K antagonists concomitantly with Pravastatin Sodium might increase the results of blood tests used to monitor the treatment with vitamin K antagonists.
- 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 Pravastatin Sodium. Taking Pravastatin Sodium with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

It is important that you tell your doctor about all the medicines you are taking, including those you have bought without a prescription.

Using Pravastatin Sodium Tablets with food and drink:
- Taking food and drink has no influence on your treatment with Pravastatin Sodium Tablets.
- Take the advise of your doctor before taking grape fruit juice with Pravastatin Sodium Tablets.
- You should always keep your alcohol intake to a minimum. If you are concerned about how much alcohol you can drink while you are taking this medicine, discuss with your doctor if you drink alcohol and seek his advice.

Pregnancy and breast-feeding:
Do not take Pravastatin if you are pregnant, trying to become pregnant or suspect you may be pregnant, as the safety in pregnant women has not been established, if you become pregnant while using Pravastatin, you must stop taking tablets immediately and contact your doctor.
A small amount of the active substance of Pravastatin passes into breast milk.
Therefore, you must not take Pravastatin while breast-feeding.
Ask your pharmacist or doctor for advice before taking any medicine.

Driving and using machines:
- Pravastatin Sodium Tablets usually does not affect your ability to drive but if you experience dizziness make sure you are fit to drive or operate machinery.

Important information about some of the ingredients of Pravastatin Sodium Tablets.
This medicine contains lactose.
If you have been told by your doctor that you have intolerance to some sugars (eg. Lactose), contact your doctor before taking this medicinal product.

3. How to take Pravastatin Sodium Tablets

Always take your tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
- Pravastatin Sodium Tablets can be taken with or without food. Swallow the correct number of tablets with glass of water.
- You should continue taking Pravastatin Sodium Tablets as long as your doctor has advised you to do so. This will vary from person to person and your doctor will adjust the number and strength of the tablets to suit you.

Dose instructions for adults and adolescents (14-18 years)
- In the treatment of high level of cholesterol and fats in the blood: The usual dose of Pravastatin Sodium is 10-40 mg once a day preferably in the evening.

- In the prevention of heart and blood vessel diseases: the usual dose is 40 mg once a day, preferably in the evening.

The maximum daily dose of 40 mg of pravastatin should not be exceeded. Your doctor shall tell you which dose suits you.

Dose instructions for children (8-13 years)
The usual dose is 10-20 mg once a day.

After organ transplant:
Your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.
If you are also taking a medicine which lowers the body's immune system (ciclosporin), your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.
If you suffer from kidney or severe liver disease, your doctor may prescribe a lower dose of Pravastatin Sodium to you.
If you have the impression that the effect of this treatment is too strong or too weak, talk to your doctor or pharmacist.

Duration of treatment
Your doctor will indicate the duration of your treatment with Pravastatin Sodium. This medicine must be used very regularly and for as long as your doctor advises, even if it is for a very long time. Do not stop your treatment by yourself.

If you take more Pravastatin Sodium Tablets than you should
If you take more tablets than you have been told to take, or if someone else accidentally takes your medicine, contact accident and emergency department of your nearest hospital for appropriate advice. Take any left over tablets or empty box with you for easier identification.

If you forget to take Pravastatin Sodium Tablets
If you miss a dose, simply take your usual dose when it is next due.
Do not take a double dose to make up for the forgotten dose, take your next dose as usual and continue your course.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pravastatin Sodium Tablets can cause side effects, although not everybody gets them.

The patient is advised to stop taking the tablets and seek immediate medical attention should they experience any of these effects**.**
- Hypersensitivity reactions (angioneurotic oedema, anaphylaxis) such as serious allergic reactions with swelling of the face, tongue and wind pipe which can cause great difficulty in breathing.
- Problems with touch (burning / tingling sensation or numbness or pins and needles (paresthesia) may occur which may be a sign of damage to the nerve endings (peripheral polyneuropathy)
- Rarely, patients have developed muscle wasting or inflammation, and very rarely this has progressed to become a serious potentially life-threatening condition (called 'rhabdomyolysis'). Acute renal failure secondary to myoglobinuria (the presence of myoglobin in the urine), myositis (inflammation of muscles), myopathy (muscle disease), polymyositis (chronic muscle inflammation) may be associated with rhabdomyolysis. If you have muscle weakness, tenderness or pain and particularly at the same time, you feel unwell or have a high temperature, stop taking Pravastatin Sodium Tablets and tell your doctor immediately.
- Tendon disorders complicated by rupture.
- Yellowish discolouration of the skin (jaundice), tissues and body fluids.
- Hepatitis (Inflammation of liver), acute liver failure

Very rare (may affect up to 1 in 10,000 people) :
- Pancreatitis (Inflammation of the pancreas)
- Chronic inflammatory autoimmune disorder (An illness that occurs when the body tissues are attacked by its own immune system), a certain type of chronic skin disorder (lupus like syndrome).
- Increases in transaminases (a group of enzymes occurring naturally in the blood) which may be a sign of liver problems. Your doctor may want to perform tests periodically to check these.

Uncommon (may affect up to 1 in 100 people) :
- Dizziness
- Headache
- Sleep disturbances
- Insomnia (sleeplessness)
- Vision disturbance (blurred vision or double vision)
- Dyspepsia (difficulty in digesting food)/ heartburn
- Abdominal pain
- Nausea(urge to vomit)/ Vomiting
- Constipation
- Diarrhoea
- Flatulence
- Skin reactions like itching and rashes
- Scalp and hair problems (including hair loss)
- Abnormal urination (pain,frequent urination at night)
- Disturbed sexual functions
- Fatigue (tiredness)

Not Known (frequency cannot be estimated from the available data):
- Muscle weakness that is constant.

Possible side-effects
- Nightmares
- Memory loss
- Depression
- Breathing problems including persistant cough and/or shortness of breath or fever
- Dermatomyositis (condition characterized by an inflammation of the muscles and the skin).

Diabetes mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose at 5.6 mmol/L, BMI>30kg/m 2, raised triglycerides, history of hypertension. 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 will monitor you while you are taking this medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

For United Kingdom
You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/Yellow Card in the Google Play or Apple App Store.

For Ireland
You can also report side effects directly via
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website:www.hpra.ie
e-mail: medsafety@hpra.ie

For Malta
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

5. How to store Pravastatin Sodium Tablets

- Keep out of reach and sight of children.
- Store below 25°C. Store in the original package in order to protect from light and moisture.
- Do not use the tablets after the expiry date stated on the carton and blister (EXP). The expiry date refers to the last day of that month
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Further information

What Pravastatin Sodium Tablets contains:
The active ingredient is Pravastatin Sodium. Pravastatin Sodium tablets have either 10 mg, 20 mg or 40 mg Pravastatin Sodium in them. The other ingredients in the tablet are: microcelac, lactose monohydrate, povidone, croscarmellose sodium, magnesium stearate, magnesium oxide light and yellow iron oxide (E 172).

What Pravastatin Sodium Tablets looks like and content of the pack:
Pravastatin Sodium 10 mg Tablets are yellow coloured, rounded rectangular shaped, biconvex, uncoated tablets debossed 'PDT' on one side and '10' on the other side.
Pravastatin Sodium 20 mg Tablets are yellow coloured, rounded rectangular shaped, biconvex, uncoated tablets debossed 'PDT' on one side and '20' on the other side.
Pravastatin Sodium 40 mg Tablets are yellow coloured, rounded rectangular shaped, biconvex, uncoated tablets debossed 'PDT' on one side and '40' on the other side.
Pravastatin Sodium Tablets are packed in blisters and are available in pack sizes containing 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 or 100 tablets.
Not all pack sizes may be marketed

Marketing Authorization holder and Manufacturer:

Marketing Authorization holder
United Kingdom
Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom

Ireland/Malta
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer
Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice,
Poland

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