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PATIENT INFORMATION LEAFLET

LIPITOR[®] 10mg, 20mg, 40mg and 80mg TABLETS Atorvastatin calcium

Please read this leaflet

Please read this leaflet carefully before you start to take LIPITOR. It contains important information about your treatment. If you have any questions, or if you are not sure about anything, ask your doctor or pharmacist. Keep this leaflet, you may want to read it again.

What is in your medicine?

The name of your medicine is LIPITOR. It comes as white oval film-coated tablets containing atorvastatin calcium trihydrate equivalent to 10, 20, 40 or 80 mg of the active ingredient atorvastatin. The tablets are stamped with 10, 20, 40 or 80 on one side and an identification number on the other side. Each strength of LIPITOR is supplied in blister packs of 28 tablets. The 10 mg and 20 mg strengths are also supplied in a sample pack size of 7 tablets.

LIPITOR Tablets also contain the inactive ingredients: calcium carbonate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose and magnesium stearate.

The coating of LIPITOR contains hypromellose, macrogol 8000, titanium dioxide, talc, simeticone, macrogol stearate and sorbic acid. The 10, 20 and 40 mg tablets also contain candelilla wax.

Marketing Authorisation Holder

Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.

Manufacturers

Goedecke GmbH, Mooswaldallee 1, D-79090 Freiburg, Germany.

What is LIPITOR for?

LIPITOR belongs to a group of medicines known as lipid regulating medicines (of the type commonly known as statins). It is used in adults to lower fats known as cholesterol and triglycerides in your blood when a low fat diet and other non-medicinal treatments such as exercise and lifestyle changes have failed. Cholesterol is a naturally occurring substance in the body necessary for normal growth. However, if there is too much cholesterol in your blood it can be deposited in the walls of blood vessels leading to the narrowing of these vessels which may eventually become blocked. This is one of the most common causes of heart disease. It is accepted that raised cholesterol levels increase the risk of heart disease. Other factors including high blood pressure, diabetes, increased weight, lack of exercise and smoking will add to the risk of heart disease.

If you are at an increased risk of heart disease, LIPITOR can also be used to reduce such risk even if your cholesterol levels are normal. A standard cholesterol lowering diet should be continued during treatment.

Before you use LIPITOR

Do you have kidney problems, underactive thyroid gland (hypothyroidism) any muscle disorders (affecting either yourself or other members of your family), previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines), or a history of heavy alcohol consumption. If the answer is **'yes'** to any of these questions your doctor will need to carry out a blood test before and possibly during your LIPITOR treatment. These blood tests will be used to predict your risk of muscle-related side-effects. A blood test may also be required if you are older than 70 years in order to determine your risk of muscle-related side-effects. The risk of muscle-related side-effects, eg rhabdomyolysis, is known to increase when certain medicines are taken at the same time (see below). Your doctor will consider this in deciding upon your dose of LIPITOR.

If you have previously had a stroke due to bleeding in the brain, Lipitor 80mg Tablets may not be suitable for you. Your doctor will be able to discuss this with you.

If the answer is **'yes'** to any of the following questions, do not take LIPITOR. Talk to your doctor or pharmacist at once.

- Are you a woman able to have children not using adequate contraceptive measures?
- Are you pregnant, trying to become pregnant or breast-feeding?
If you are trying to become pregnant your doctor will advise you to stop taking LIPITOR about one month before you plan to conceive.
- Have you ever had a reaction to LIPITOR or to any similar medicines used to lower blood lipids or to any of the inactive ingredients of the medicine?
- Do you have or have you had a disease which affects the liver? Have you had any unexplained abnormal blood tests for liver function?
- Do you drink excessive amounts of alcohol that might be affecting your liver?

- Has your doctor told you that you suffer from a condition causing muscle pain and/or weakness?
- Has your doctor told you that you have an intolerance to some sugars?

Can you take LIPITOR with other medicines?

There are some medicines that may change the effect of LIPITOR, or their effect may be changed by LIPITOR. 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 muscle wasting condition known as rhabdomyolysis:

- Medicines used to modulate immune response, e.g. ciclosporin.
- Macrolide antibiotics, e.g. erythromycin, clarithromycin; azole antifungal medicines, e.g. ketoconazole, itraconazole; rifampin (an antibiotic).
- Medicines to regulate lipid levels, e.g. fibric acid derivatives, niacin.
- Medicines to regulate your heart rhythm, e.g. amiodarone, or blood pressure, e.g. diltiazem.
- Medicines used in the treatment of HIV e.g. nelfinavir, efavirenz
- Digoxin, warfarin, oral contraceptives, antacids

When taking LIPITOR, do not drink more than two small glasses of grapefruit juice per day, that is no more than around 200ml in total.

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

How to take LIPITOR

The usual starting dose of LIPITOR is 10 mg once a day. This may be increased if necessary by your doctor until you are taking exactly the amount you need. Do not drink more than two small glasses of grapefruit juice per day (200ml in total). Remember to continue with your diet and lifestyle changes while you are taking LIPITOR.

What if you miss a dose?

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take 2 doses at the same time.

What if you take too many tablets?

If you accidentally take too many LIPITOR Tablets, tell your doctor at once. If you cannot do this, go to the nearest hospital accident and emergency department. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

Does LIPITOR cause side-effects?

As with all medicines, LIPITOR can sometimes cause side-effects in some individuals. The most commonly reported ones are:

- Nausea, abdominal pain, constipation, wind, indigestion, headache, muscle pain, weakness, diarrhoea and insomnia.

Other less common side-effects have been seen in some patients taking LIPITOR or other medicines of this kind. These include:

- Muscle cramps, weakness or tenderness, numbness or tingling in the fingers and toes, impotence, pancreatitis (inflammation of the pancreas leading to stomach pain), hepatitis (liver inflammation), jaundice (yellowing of the skin and whites of the eyes), liver failure, loss of appetite, vomiting, hair loss, itching, rash (rarely severe blistering rash with associated general illness), chest pain, dizziness, allergic reactions, joint pain, loss of memory, back pain, weight gain, oedema (e.g. ankle swelling), feeling tired, noises in the ears and/or head, reduction in sensation of skin to light, touch or pain, change in sense of taste, visual disturbances, hearing loss, breast enlargement in men, and tendon injury.
- Angioneurotic oedema (swelling of the face, tongue and wind pipe which can cause great difficulty in breathing). This is a very rare reaction which can be serious if it occurs. You should tell your doctor immediately if it happens.
- Rarely, patients have developed muscle wasting or inflammation, and very rarely this has progressed to become a serious potentially life-threatening condition (called '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 LIPITOR and tell your doctor immediately. Consult your doctor as soon as possible if you experience any unexplained or persistent muscle aches especially if you are feeling unwell or have a fever or if you experience symptoms suggestive of liver complaint (see above).
- Abnormal blood tests: increases or decreases in blood sugar, problems with bleeding and bruising, 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.

If you get any of these, or any other unusual effects, tell your doctor or pharmacist at once.

How to store LIPITOR

- Do not use LIPITOR after the last day of the month shown in the expiry date. This will be printed on the outside of the pack and also on the blister foil.
- This medicinal product does not require any special storage conditions
- As with all medicines, keep LIPITOR **out of reach and sight of children.**

Remember

This medicine is for you. Only your doctor can prescribe LIPITOR for you. Never give it to anyone else. It may harm them even if their condition is the same as yours.

If you have any further questions about your medicine or your treatment, ask your doctor or pharmacist.

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