PATIENT INFORMATION LEAFLET

Please read all of this leaflet carefully before you start taking this medicinal product.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicinal product has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Tulip® 10 mg / 20 mg – film coated tablets

SANDOZ

In this leaflet:

Tulip® 10 mg - film coated tablets
Tulip® 20 mg - film coated tablets

ATORVASTATIN

The active substance: atorvastatin

Other ingredients:
Tulip 10 mg film coated tablets:
Core: microcrystalline cellulose; lactose monohydrate; croscarmellose sodium; hydroxypropyl cellulose; polysorbate 80; magnesium oxide; colloidal anhydrous silica; magnesium stearate.
Coating: hydroxypropylmethylcellulose; hydroxypropyl cellulose; titanium dioxide (E 171); macrogol 6000; talc.

Tulip 20 mg film coated tablets:
Core: microcrystalline cellulose; lactose monohydrate; croscarmellose sodium; hydroxypropyl cellulose; polysorbate 80; magnesium oxide; colloidal anhydrous silica; magnesium stearate.
Coating: hydroxypropylmethylcellulose; hydroxypropyl cellulose; titanium dioxide (E 171); macrogol 6000; ferric oxide, yellow (E 172); talc.

Marketing authorisation holder: Sandoz GmbH, Kundl, Austria
Manufacturer:
Lek Pharmaceuticals d.d., Verovškova 57, Ljubljana, Slovenia

1. WHAT TULIP TABLETS ARE AND WHAT THEY ARE USED FOR

Each 10 mg film coated tablet contains 10 mg of atorvastatin in the form of calcium salt.
Each 20 mg film coated tablet contains 20 mg of atorvastatin in the form of calcium salt.
This medicinal product is packed in:
Boxes with three blister packs of 10 film coated tablets containing 10 mg of atorvastatin.
Boxes with three blister packs of 10 film coated tablets containing 20 mg of atorvastatin.
Tulip tablets are used to reduce elevated blood lipid levels.
Tulip tablets lower increased level of cholesterol and triglycerides in blood when other measures (eg. dietary modification, physical activity, loss of weight) failed in patients with:
– elevated blood cholesterol levels (primary hypercholesterolemia which corresponds to Fredrickson type IIa);
– concurrent increases in cholesterol and triglyceride levels in blood (mixed hyperlipidemia, which corresponds to Fredrickson type IIb);
– hereditarily increased cholesterol plasma levels in familial hypercholesterolemia.

2. BEFORE YOU USE TULIP TABLETS

Prior to treatment liver function tests shall be performed and repeated regularly during the therapy. Should an increase in liver function test values attain three times the normal value and last for longer period of time, dose reduction or complete discontinuation of therapy with Tulip tablets is recommended.

In patients taking atorvastatin muscle pain may occur from time to time (uncomplicated myalgia). In subjects with signs and symptoms of muscle diseases (myopathy), tests for assessment of possible increases of muscle enzymes level (CPK) in blood shall be performed. Should a substantial increase in CPK levels persist for longer period of time, dosage is to be lowered or atorvastatin treatment even completely withdrawn. Tell your doctor if muscle aches, tenderness or weakness arise.

Do not use Tulip if:
– you are hypersensitive to any component of this medicinal product;
– you have liver disease, or unexplained and persistent elevation in liver function tests (serum transaminases) was found;
– you have any disease of skeletal muscles;
– you are pregnant or might become pregnant;
– you are breast-feeding.

Special precautions for use:
Take Tulip tablets with great caution if:
– you consume substantial quantities of alcohol,
– you have or have had a history of liver disease.
You should also advise your doctor of these conditions. You must also tell him/her if you take any other medicinal product.

Use of Tulip tablets with food and drink
If you consume great amounts of alcohol, you should take Tulip tablets with great caution.

Pregnancy and lactation
If you are pregnant or breast-feeding, you should not take atorvastatin. Women of child-bearing age may take Tulip tablets only if appropriate contraception is provided. Safety of atorvastatin use during pregnancy and breast-feeding has not been established yet.

Driving and using machines
There are no data available that Tulip tablets would affect the ability to drive motor vehicles or use machines.

Important information about the ingredients of Tulip tablets
There are no non-standard excipients in the composition of the product.

Taking other medicinal products
Interactions occur during coadministration of related medicinal products of this class (HMG-CoA reductase inhibitors), drugs inhibiting the immune response of the body (eg. cyclosporine), other lipid-lowering agents (eg. fibrates, nicotinic acid derivatives), the antibiotic erythromycin, or azole antifungals. The level of muscle enzyme CPK is increased and there may also appear muscle aches. In rare cases disintegration of skeletal muscles (rhabdomyolysis) with renal failure occurs. You may take these medicinal products and macrolide antibiotics concurrently with Tulip tablets only as specifically directed by the physician.
The result of colestipol and atorvastatin coadministration is greater decrease of blood lipid levels.
In concurrent administration of atorvastatin and digoxin and some oral contraceptives plasma concentrations of these medicinal products are increased.
Your doctor will consider all this when he/she will establish the doses of these medicinal products.
Coadministration of drugs reducing gastric acid contents (antacids containing magnesium and aluminium) results in decreased plasma concentrations of atorvastatin whose effect on lowering cholesterol concentration is thus not lowered.
Concurrent erythromycin administration increases atorvastatin concentration in plasma.
Patients receiving warfarin, the product which inhibits blood coagulation, concurrently with Tulip tablets, should be under strict medical supervision (particularly at the onset of therapy).
These precautions for use refer also to medicinal products which you have been taking a short time before atorvastatin administration.

3. HOW TO USE TULIP TABLETS

The following instructions apply only if your doctor has not prescribed you another manner of administration of Tulip tablets. You shall follow closely the instructions; in the opposite case the medicinal product will not fully exert its activity.
Before the beginning of treatment your doctor will prescribe you low-cholesterol diet. You should strictly follow this diet during treatment with Tulip tablets.
The usual starting dose is 10 mg of atorvastatin once a day. The doctor will titrate further doses so that you will achieve the desired blood cholesterol level. Thereafter he/she will adjust the atorvastatin dose individually every four weeks or less frequently; the maximum daily dosage of atorvastatin is 80 mg.
You may take Tulip tablets with some liquid at any time of the day and regardless of food intake. Tulip tablets are designated for long-term administration.

Elevated blood cholesterol levels (hypercholesterolemia) or concurrent elevation of cholesterol and triglyceride concentrations in blood (mixed hyperlipidemia)
In the majority of patients the efficient daily dose of atorvastatin is 20 mg. The effect of treatment may be observed after two weeks; it is the highest after four weeks, as a rule. This therapeutic effect is then maintained with long-term administration of the product.

Hereditary increase of blood cholesterol levels (familial hypercholesterolemia)
– Heterozygous familial hypercholesterolemia
The starting dose is 10 mg of atorvastatin once a day. The dose should be determined for each individual patient by his/her doctor. The doctor will also prescribe you dose increases every four weeks up to 80 mg daily.

Homozygous familial hypercholesterolemia
Adults: In the majority of patients (taking 80 mg of atorvastatin daily), cholesterol level (LDL cholesterol) in blood decreased by 17 to 31 percent in the clinical trials.

Children: Clinical experience in the treatment of children with atorvastatin is limited. The recommended daily dosage of atorvastatin is 10 mg. It may be increased up to 80 mg daily, depending on the efficiency of the medicinal product and its tolerance.

Dosage in patients with renal insufficiency and in older patients
Kidney diseases do not affect treatment with Tulip tablets. Thus, dosage adjustment of the medicinal product in patients with renal insufficiency is not necessary.
In clinical trials it was ascertained that drug dosage in eldelly patients does not need any adjustment either.

What you should do if you took more Tulip tablets than you should
In the event of an overdose of atorvastatin, no special treatment is needed; you should, however, inform your doctor of ingestion of an excessive dose of the medicinal product.

What you should do if you forgot to take Tulip tablets
If you missed a dose of tablets do not take a double dose, but only the normal dose.

4. POSSIBLE ADVERSE EVENTS

Tulip tablets are generally well tolerated. Adverse events are usually mild and transient.
In more than one percent of patients administered atorvastatin, constipation, flatulence, abdominal pain, headache, nausea, muscle aches (myalgia), diarrhoea and insomnia occurred.

Like in all patients taking other medicinal products of this class, increases in liver function tests (transaminoses) were also observed in patients administered atorvastatin. These alterations are usually insignificant and transient and do not necessitate interruption of treatment.

Elevated serum creatine phosphokinase (CPK) levels were also occasionally established in patients. In rare cases this was related with muscle pain, tenderness or weakness.

In clinical studies with atorvastatin the following adverse events were also observed, yet their direct connection with atorvastatin administration has not been established in all cases: muscle inflammation (myositis), muscle disease (myopathy), formication (paresthesia), noninflammatory diseases of nerves (peripheral neuropathy), inflammation of the pancreas, inflammation of the liver, jaundice, increased appetite, vomiting, hair loss, pruritus, skin rash, impotence, increased or decreased blood sugar level.

Chest pain, dizziness and photosensitivity reactions were also noted in individual patients.

If you notice any adverse events of this medicinal product you should tell your doctor, who will decide which measures to undertake. If the liver function tests are increased and attain more than three fold the normal value, or if this increase in CPK levels persists for some time, your doctor will reduce the dose of the product or interrupt treatment with Tulip tablets.

You should inform your doctor or pharmacist also if you notice any adverse events not mentioned in this leaflet.

5. STORING AND EXPIRY DATE

Keep the medicinal product out of reach of children.

Do not store above 30° C.
Store the medicine in the original package.

Do not use the medicinal product after the expiry date indicated on the package.

Availability
The medicinal product is available on prescription only.

Prepared
March 2001

Manufactured by Lek Pharmaceuticals d.d., Verovškova 57, Ljubljana, Slovenia for Sandoz GmbH, Kundl, Austria

NOTICE

Veuillez lire attentivement l'intégralité de cette notice avant de prendre ce médicament.
- Gardez cette notice, vous pourriez avoir besoin de la relire.
- Si vous avez d'autres questions, si vous avez un doute, demandez plus d'informations à votre médecin ou votre pharmacien.
- Ce médicament vous a été personnellement prescrit. Ne le donnez jamais à quelqu'un d'autre, même en cas de symptômes identiques. Cela pourrait lui être nocif.

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