PATIENT INFORMATION LEAFLET
(VAST-20) ATORVASTATIN TABLETS 20 MG
[Atorvastatin Calcium]

Read all of this leaflet carefully before you start using this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your physician, health care provider 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 physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What atorvastatin tablets is and what it is used for
2. Before you use atorvastatin tablets
3. How to use atorvastatin tablets
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1. WHAT ATORVASTATIN TABLETS IS AND WHAT IT IS USED FOR

It contain active ingredient atorvastatin anhydrous is an anhydrous calcium salt form of atorvastin, a synthetic lipid-lowering agent. It works by slowing the production of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and other parts of the body. It is used to treatment in Hypercholesterolaemia and Prevention of cardiovascular disease.

2. BEFORE YOU USE ATORVASTATIN TABLETS

Do not use it if you are allergic to atorvastatin or any of the other ingredients of this medicine. It is contraindicated in: Patients with hypersensitivity to the active substance or to any of the excipients of this medicinal product. Patients with active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal. Patients with myopathy. During pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures. Atorvastatin is not indicated in the treatment of patients below the age of 10 years. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having atorvastatin tablets.

Take special care with atorvastatin tablets : Talk to your physician before taking atorvastatin tablets. Patients with history of liver disease or high alcohol intake. Patients with risk factor of myopathy or rhabdomyolysis.

Warnings and Precautions: Pregnancy: HMG-CoA reductase inhibitors are contraindicated in pregnancy. It should not be recommended during pregnancy. **Lactation:** It is not known whether this drug is excreted in human milk. Because of the potential for adverse reactions in nursing infants, women taking should not breast-feed.

Using other medicines: Cytochrome P450 3A4 inhibitors: Co-administration of potent CYP3A4 inhibitors (e.g. ciclosporin, telithromycin, clarithromycin, delavirdine, stiripentol, ketoconazole, voriconazole, itraconazole, posaconazole and HIV protease inhibitors including ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.) should be avoided. **CYP3A4 inducers:** Concomitant administration of atorvastatin with inducers of cytochrome P450 3A (e.g.efavirenz, rifampin, St. John's Wort) can lead to variable reductions in plasma concentrations of atorvastatin. **Transport protein inhibitors:** Inhibitors of transport proteins (e.g. ciclosporin) can increase the systemic exposure of atorvastatin. If concomitant administration, a dose reduction and clinical monitoring for efficacy is recommended**. Gemfibrozil /fibric acid derivatives:** The risk of muscle related events, including rhabdomyolysis may be increased with the concomitant use of fibric acid derivatives and atorvastatin. **Ezetimibe:** The risk of muscle related events, including rhabdomyolysis may be increased with concomitant use of ezetimibe and atorvastatin. **Colestipol:** When colestipol was co-administered with Atorvastatin plasma concentrations of atorvastatin and its active metabolites is lower (by approx. 25%). However, lipid effects of atorvastatin are greater when atorvastatin and colestipol were co-administered than when either medicinal product was given alone. **Oral contraceptives:** Co-administration of atorvastatin with an oral contraceptive produced increases in plasma concentrations of norethindrone and ethinyl oestradiol.

Using atorvastatin tablets with food and drink: Patients can take this medicine with or without food. It should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease.

Pregnancy and breast-feeding: Before taking any medicine for advice consult to direction of physician. **Pregnancy:** HMG-CoA reductase inhibitors are contraindicated in pregnancy. It should not be recommended during pregnancy**. Lactation:** It is not known whether this drug is excreted in human milk. Because of the potential for adverse reactions in nursing infants, women taking should not breast-feed.

Driving and using machines: It has negligible influence on the ability to drive and use machines.

Important information about some of the ingredients of atorvastatin tablets contains: Each film coated tablet contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

3. HOW TO USE ATORVASTATIN TABLETS

Always take your dose of atorvastatin tablets exactly as direction by physician or a nurse or health care provider or pharmacist has told you, if you are not sure. Do not change your usual dose without talking to your physician.

How atorvastatin tablets will be given to you: Route of administration: orally with or without regard to food intake. As directed by physician.

Adults: Primary hypercholesterolaemia and combined (mixed) hyperlipidaemia: Initially: 10 or 20 mg daily may increase at 4-week intervals. May initiate with 40 mg once daily in patients who require >45% reduction in low-density lipoprotein cholesterol. **Maximum dose:** 80 mg/day.

Heterozygous familial hypercholesterolaemia: Initial: 10 or 20 mg once daily, may increase slowly if needed. Maximum: 80 mg/day.

Prevention of cardiovascular disease: Initial: 10 mg daily. Higher doses may be necessary in order to attain (LDL-) cholesterol levels or as directed by physician.

Pediatric use: Hypercholesterolaemia: 10 mg once daily; maximum recommended dose: 20 mg once daily.

Hepatic impairment: Atorvastatin should be used with caution in patients with hepatic impairment.

If you more atorvastatin tablets than you should: the over dosage is unlikely to oral route. By accident, anyone take this medicine, experience with Atorvastatin overdosage is limited, No specific treatment for atorvastatin overdose is available. In case of an overdose the patient should be treated symptomatically and supportive measures should be instituted. Liver function and serum CPK values monitored.

If you forget to atorvastatin tablets: It is important to take atorvastatin tablets as prescribed by your physician. Do not take a double dose to make up for the missed dose. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Like all medicines, it can cause side effects, although not everybody gets them. Following adverse effects have been reported with oral administration of atorvastatin: Infections and infestations: Nasopharyngitis. Blood and lymphatic system disorders: Thrombocytopenia. Immune system disorders: Allergic reactions. Metabolism and nutrition disorders: Hyperglycaemia, hypoglycaemia, weight gain, anorexia. Nervous system disorders: Headache, dizziness, paraesthesia, hypoesthesia, amnesia. Respiratory, thoracic and mediastinal disorders: Pharyngolaryngeal pain, epistaxis. Gastrointestinal disorders: Constipation, flatulence, dyspepsia, nausea, diarrhoea. Skin and subcutaneous tissue disorders: Urticaria, skin rash, pruritus, alopecia. Musculoskeletal and connective tissue disorders: Myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain. Miscellaneous: Liver function test abnormal, blood creatine kinase increased.

5. HOW TO STORE ATORVASTATIN TABLETS

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as Atorvastatin calcium. Excipients as: Calcium Carbonate, Lactose (Lactose Monohydrate), Microcrystalline Cellulose (pH 102), Povidone (P.V.P.K.-30), Polysorbate-80, Croscarmellose Sodium, Magnesium Stearate, Opadry White YS-1-7040, Polysorbate-80, Simethicone 30% , Puified Water Pack size: White to off-white coloured, round shaped, biconvex, film coated tablets, breakline on one side and plain on other side. Atorvastatin tablets filled in Alu-Alu blisterpacked. 10 Tablets are packed in Alu-Alu blister Pack. Such 3 blister packed in a printed Carton with Packing Insert.

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