Bharat Parenterals Limited
Registered Office & Works:
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CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Atorvastatin Tablets 10 mg

Trade Name: Levastor 10

1.2 Strength:

Atorvastatin 10 mg

1.3 Pharmaceutical form:

Solid oral dosage form- Tablet

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Label Claim (mg)	Qty./Tablet (mg)	% w/w	Function
Dry Mixing						
1.	Atorvastatin Calcium eq to Atorvastatin	USP	10.00	10.000	3.79	Active
2.	Microcrystalline Cellulose	BP	–	229.200	86.95	Diluent
Lubrication						
3.	Purified talc	BP	–	4.000	1.52	Glidant
4.	Magnesium Stearate	BP	–	2.800	1.06	Lubricant
5.	Croscarmellose Sodium	BP	–	6.000	2.28	Disintegrant
6.	Crospovidone	BP	–	8.000	3.03	Disintegrant
Total weight of Uncoated tablets				**260.000 mg**		
Film Coating						
7.	Isopropyl alcohol	BP	–	32.400	–	Solvent
8.	Dichloromethane	BP	–	48.600	–	Solvent
9.	COL. Elegance Coat EL-W-1001White	IH	–	3.600	1.37	Colorant
Total Weight of film coated Tablet				**263.600 mg**	**100.00 %**	–

3. Pharmaceutical form:

Dosage Form: Solid oral dosage form- Tablet

Visual & Physical characteristics of the product:

A white coloured round shape, biconvex, film coated tablets.

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4. Clinical particulars

4.1. Therapeutic indications:

The following indications are restricted to adults.

Hypercholesterolaemia

Atorvastatin Tablets 10 mg is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

Atorvastatin Tablets 10 mg is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Prevention of cardiovascular disease

Prevention of cardiovascular events in adults estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

4.2. Posology and method of administration:

Posology

The patient should be placed on a standard cholesterol-lowering diet before receiving Atorvastatin and should continue on this diet during treatment with Atorvastatin.

The dose should be individualised according to baseline LDL-C levels, the goal of therapy, and patient response.

The usual starting dose is 10mg once a day. Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day.

Primary hypercholesterolaemia and combined (mixed) hyperlipidaemia

The majority of patients are controlled with Atorvastatin 10mg Film coated Tablets once a day. A therapeutic response is evident within 2 weeks, and the maximum therapeutic response is usually achieved within 4 weeks. The response is maintained during chronic therapy.

Heterozygous familial hypercholesterolaemia

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Patients should be started with Atorvastatin 10mg Film coated Tablets daily. Doses should be individualised and adjusted every 4 weeks to 40 mg daily. Thereafter, either the dose may be increased to a maximum of 80 mg daily or a bile acid sequestrant may be combined with 40 mg atorvastatin once daily.

Homozygous familial hypercholesterolaemia

Only limited data are available

The dose of atorvastatin in patients with homozygous familial hypercholesterolaemia is 10 to 80 mg daily. Atorvastatin should be used as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) in these patients or if such treatments are unavailable.

Prevention of cardiovascular disease

In the primary prevention trials the dose was 10mg/day. Higher doses may be necessary in order to attain (LDL-) cholesterol levels according to current guidelines.

Renal impairment

No adjustment of dose is required

Hepatic impairment

Atorvastatin should be used with caution in patients with hepatic impairment. Atorvastatin is contraindicated in patients with active liver disease.

Co-administration with other medicines

In patients taking hepatitis C antiviral agents elbasvir/grazoprevir or letermovir for cytomegalovirus infection prophylaxis concomitantly with atorvastatin, the dose of atorvastatin should not exceed 10 mg/day.

Use of atorvastatin is not recommended in patients taking letermovir co-administered with ciclosporin.

Elderly

Efficacy and safety in patients older than 70 using recommended doses are similar to those seen in the general population.

Paediatric population

Hypercholesterolaemia:

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Paediatric use should only be carried out by physicians experienced in the treatment of paediatric hyperlipidaemia and patients should be re-evaluated on a regular basis to assess progress.

For patients with Heterozygous Familial Hypercholesterolaemia aged 10 years and above, the recommended starting dose of atorvastatin is 10mg per day. The dose may be increased to 80 mg daily, according to the response and tolerability. Doses should be individualised according to the recommended goal of therapy. Adjustments should be made at intervals of 4 weeks or more. The dose titration to 80 mg daily is supported by study data in adults and by limited clinical data from studies in children with Heterozygous Familial Hypercholesterolaemia.

There is limited safety and efficacy data available in children with Heterozygous Familial Hypercholesterolaemia between 6 to 10 years of age derived from open-label studies. Atorvastatin is not indicated in the treatment of patients below the age of 10 years.

Other pharmaceutical forms/strengths may be more appropriate for this population.

Method of administration

Atorvastatin Film-coated Tablets is for oral administration. Each daily dose of atorvastatin is given all at once and may be given at any time of day with or without food.

4.3. Contraindications:

Atorvastatin is contraindicated in patients:

- with hypersensitivity to the active substance or to any of the excipients
- with active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal
- during pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures.
- treated with the hepatitis C antivirals glecaprevir/pibrentasvir.

4.4. Special warnings and precautions for use:

Liver effects

Liver function tests should be performed before the initiation of treatment and periodically thereafter. Patients who develop any signs or symptoms suggestive of liver injury should have liver function tests performed. Patients who develop increased transaminase levels

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should be monitored until the abnormality(ies) resolve. Should an increase in transaminases of greater than 3 times the upper limit of normal (ULN) persist, reduction of dose or withdrawal of Atorvastatin 40mg Film coated Tablets is recommended. Atorvastatin 40mg Film coated Tablets should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease.

Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL)

In a post-hoc analysis of stroke subtypes in patients without coronary heart disease (CHD) who had a recent stroke or transient ischemic attack (TIA) there was a higher incidence of haemorrhagic stroke in patients initiated on atorvastatin 80 mg compared to placebo. The increased risk was particularly noted in patients with prior haemorrhagic stroke or lacunar infarct at study entry. For patients with prior haemorrhagic stroke or lacunar infarct, the balance of risks and benefits of atorvastatin 80 mg is uncertain, and the potential risk of haemorrhagic stroke should be carefully considered before initiating treatment.

Skeletal muscle effects

Atorvastatin, like other HMG-CoA reductase inhibitors, may in rare occasions affect the skeletal muscle and cause myalgia, myositis, and myopathy that may progress to rhabdomyolysis, a potentially life-threatening condition characterised by markedly elevated creatine kinase (CK) levels (> 10 times ULN), myoglobinaemia and myoglobinuria which may lead to renal failure.

There have been very rare reports of an immune-mediated necrotizing myopathy (IMNM) during or after treatment with some statins. IMNM is clinically characterized by persistent proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment.

Before the treatment

Atorvastatin should be prescribed with caution in patients with pre-disposing factors for rhabdomyolysis. A CK level should be measured before starting statin treatment in the following situations:

- Renal impairment
- Hypothyroidism

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