

TG TOR EZ

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **TG TOR EZ** [Atorvastatin Calcium & Ezetimibe Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: **Atorvastatin** is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme responsible for the conversion of 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. **Ezetimibe** is in a new class of lipid-lowering compounds that selectively inhibit the intestinal absorption of cholesterol and related plant sterols. Ezetimibe is orally active and has a mechanism of action that differs from other classes of cholesterol-reducing compounds (e.g., statins, and plant stanols).

INDICATION: **TG TOR EZ** is indicated for the treatment of patients with primary hypercholesterolemia.

DOSAGE AND ADMINISTRATION: As directed by the physician. The dose should be individualised according to baseline LDL-C levels, the goal of therapy, and patient response.

CONTRAINDICATION: 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.

WARNINGS & PRECAUTIONS: Liver function tests should be performed before the initiation of treatment and periodically thereafter. Atorvastatin should be prescribed with caution in patients with pre-disposing factors for rhabdomyolysis. Efficacy and safety of Ezetimibe in patients 6 to 10 years of age with heterozygous familial or non-familial hypercholesterolemia have been evaluated in a 12-week placebo-controlled clinical trial.

DRUG INTERACTIONS: Atorvastatin is metabolised by cytochrome P450 3A4 (CYP3A4) and is a substrate of the hepatic transporters, organic anion-transporting polypeptide 1B1 (OATP1B1) and 1B3 (OATP1B3) transporter. Metabolites of atorvastatin are substrates of OATP1B1. Concomitant antacid administration decreased the rate of absorption of ezetimibe but had no effect on the bioavailability of ezetimibe.

ADVERSE REACTIONS: nasopharyngitis, allergic reactions, hyperglycaemia, nightmare, insomnia, headache, vision blurred, pharyngolaryngeal pain, epistaxis, constipation, flatulence, dyspepsia, nausea, diarrhea, myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain, liver function test abnormal, blood creatine kinase increased, hot flush; hypertension, fatigue, chest pain, pain, dry mouth; gastritis, pruritus; rash; urticarial, myalgia, back pain; muscular weakness; pain in extremity, dizziness; paraesthesia, pancreatitis; constipation, hypersensitivity, depression.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/ TG TOR EZ 10mg, 10mg/JUN-19/01/PI

(Additional information is available on request)