

TG TOR F 160

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

Abbreviated Prescribing information for [Atorvastatin Calcium & Fenofibrate Tablets I.P] **TG TOR F 160**

[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. Fenofibrate is a fibric acid derivative whose lipid modifying effects reported in humans are mediated via activation of Peroxisome Proliferator Activated Receptor type alpha (PPAR α).

INDICATION: TG TOR F 160 is indicated for the treatment of combined hyperlipidemia in patients with normal hepatic and renal function.

DOSAGE AND ADMINISTRATION: As directed by the physician. Tablet should be swallowed whole during a meal.

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: Atorvastatin should be prescribed with caution in patients with pre-disposing factors for rhabdomyolysis. Patients must be asked to promptly report muscle pain, cramps, or weakness especially if accompanied by malaise or fever. Pancreatitis has been reported in patients taking fenofibrate. This occurrence may represent a failure of efficacy in patients with severe hypertriglyceridemia

DRUG INTERACTIONS: Atorvastatin is metabolized by cytochrome P450 3A4 (CYP3A4). The use of ezetimibe alone is associated with muscle related events, including rhabdomyolysis. Drug-drug interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known

ADVERSE REACTIONS: nasopharyngitis, allergic reactions, hyperglycaemia, nightmare, insomnia, headache, vision blurred, pharyngolaryngeal pain, epistaxis, constipation, flatulence, dyspepsia, nausea, diarrhoea, myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain, liver function test abnormal, blood creatine kinase increased, hepatitis, dizziness, paraesthesia, hypoesthesia, dysgeusia, amnesia, gastric or intestinal disorders.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/ TG TOR F 10,160 mg/Sep-22/02/PI

(Additional information is available on request)