"To be sold by retail on the prescription of a Cardiologist/ Internal Medicine Specialties only"

TORPLAT

Abbreviated Prescribing information for TORPLAT (Ticagrelor Tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Torplat contains ticagrelor, a member of the chemical class cyclopentyltriazolopyrimidines (CPTP), which is an oral, direct acting, selective and reversibly binding P2Y12 receptor antagonist that prevents ADP- mediated P2Y12 dependent platelet activation and aggregation. Ticagrelor does not prevent ADP binding but when bound to the P2Y12 receptor prevents ADP-induced signal transduction. Since platelets participate in the initiation and/or evolution of thrombotic complications of atherosclerotic disease, inhibition of platelet function has been shown to reduce the risk of CV events such as death, MI or stroke. Ticagrelor also increases local endogenous adenosine levels by inhibiting the equilibrative nucleoside transporter-1 (ENT-1).

THERAPEUTIC INDICATION:

Torplat 60: Indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event.

Torplat 90: It is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST elevation Myocardial infarction (STEMI) including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).

DOSAGE AND ADMINISTRATION:

Dosage: As directed by the Physician. Patients taking

Torplat should also take a daily low maintenance dose of ASA 75-150 mg, unless specifically contraindicated.

Method of administration: For oral use. Torplat can be administered with or without food.

For patients who are unable to swallow the tablet(s) whole, the tablets can be crushed to a fine powder and mixed in half a glass of water and drunk immediately. The glass should be rinsed with a further half glass of water and the contents drunk. The mixture can also be administered via a nasogastric tube (CH8 or greater). It is important to flush the nasogastric tube through with water after administration of the mixture.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients listed. • Active pathological bleeding. • History of intracranial haemorrhage. • Severe hepatic impairment. • Co-administration of ticagrelor with strong CYP3A4 inhibitors (e.g.

ketoconazole clarithromycin, nefazodone, ritonavir and atazanavir), as co-administration may lead to a substantial increase in exposure to ticagrelor.

WARNINGS & PRECAUTIONS: **Bleeding risk** the use of ticagrelor in patients at known increased risk for bleeding should be balanced. **Surgery:** Patients should be advised to inform physicians and dentists that they are taking ticagrelor before any surgery is scheduled and before any new medicinal product is taken. **Patients with prior ischaemic stroke** ACS patients with prior ischaemic stroke can be treated with ticagrelor for up to 12 months (PLATO study). **Hepatic impairment** Use of ticagrelor is contraindicated in patients with severe hepatic impairment. **Patients at risk for bradycardic events** Holter ECG monitoring has shown an increased frequency of mostly asymptomatic ventricular pauses during treatment with ticagrelor compared with clopidogrel. **Dyspnoea** In conducted study Dyspnoea was reported in patients treated with ticagrelor. Dyspnoea is usually mild to moderate in intensity and often resolves without need for treatment discontinuation. **Creatinine elevations,:** Creatinine levels may increase during treatment with ticagrelor **Uric acid increase** Hyperuricaemia may occur during treatment with ticagrelor and **Thrombotic Thrombocytopenic Purpura (TTP).:** Thrombotic Thrombocytopenic Purpura (TTP) has been reported very rarely with the use of ticagrelor.

DRUG INTERACTION: CYP3A4 inhibitors • Strong CYP3A4 inhibitors – Co-administration of ketoconazole with ticagrelor increased the ticagrelor Cmax and AUC equal to 2.4-fold and 7.3-fold, respectively. Moderate CYP3A4 inhibitors – Co-administration of diltiazem with ticagrelor increased the ticagrelor Cmax by 69% and AUC to 2.7-fold and decreased the active metabolite Cmax by 38% and AUC was unchanged. CYP3A inducers - Co-administration of rifampicin with ticagrelor decreased ticagrelor Cmax and AUC by 73% and 86%, respectively. Cyclosporine (P-gp and CYP3A inhibitor) Co-administration of cyclosporine (600 mg) with ticagrelor increased ticagrelor Cmax and AUC equal to 2.3-fold and 2.8-fold, respectively.

ADVERSE REACTIONS: Tumour bleeding, Blood disorder bleeding, Thrombotic Thrombocytopenic Purpura, Hypersensitivity including angioedema, Hyperuricaemia, Gout/Gouty Arthritis, Confusion, Dizziness, Syncope, Headache, Intracranial haemorrhage, Eye haemorrhage, Vertigo, Ear haemorrhage, Hypotension, Dyspnoea, Respiratory system bleedings, Gastrointestinal haemorrhage, Diarrhoea, Nausea, Dyspepsia, Constipation, Retroperitoneal haemorrhage, Subcutaneous or dermal bleeding, Rash, Pruritus, Muscular bleeding, Urinary tract bleeding, Reproductive system bleedings, Blood creatinine increased and Post procedural haemorrhage, Traumatic bleedings

Marketed BY:

torrent PHARMA

IN/TORPLAT 60, 90 mg /MAR -21/02/ABPI
(Additional information is available on request)