TORPLAT A COPACK

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TORPLAT A COPACK (Combikit of Ticagrelor Tablets 90 mg and Aspirin Gastro-Resistant Tablets I.P. 75mg**)**

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

Qualitative and Quantitative composition for TORPLAT A

Each combikit contains:

(A) Ticagrelor Tablets 90 mg (14 Tablets)

Each film coated tablet contains:

Ticagrelor I.P…….90 mg

Colours: Titanium Dioxide I.P., Ferric Oxide Yellow USP-NF and Ferric Oxide Red USP-NF

(B) Aspirin Gastro-Resistant Tablets I.P. 75mg (7 Tablets)

Each enteric coated tablet contains:

Aspirin I.P. …….75 mg

(as Gastro resistant tablet I.P.)

Colour: Titanium Dioxide I.P.

The excipients used are Mannitol, Dicalcium Phosphate Dihydrate, Croscarmellose Sodium, Hydroxy Propyl Cellulose, Magnesium Stearate, Hypromellose, Titanium Dioxide, Polyethylene Glycol, Talc, Ferric Oxide Yellow, Ferric Oxide Red, Sodium Starch Glycolate, Calcium Stearate, Microcrystalline Cellulose, Instamoist shield, Isopropyl Alcohol, Methylene Chloride, Acrycoat L 100, Diethyl Phthalate and Acetone.

PHARMACOLOGICAL PROPERTIES:

Mechanism of action:

Ticagrelor:

Ticagrelor and its major metabolite reversibly interact with the platelet P2Y,2 ADP-receptor to prevent signal transduction and platelet activation. Ticagrelor and its active metabolite are approximately equipotent.

Aspirin:

Aspirin (acetylsalicylic acid) irreversibly acetylates platelet cyclo-oxygenase thereby inhibiting the biosynthesis of thromboxane, a potent vasoconstrictor and inducer of platelet aggregation. It also inhibits the action of cyclo-oxygenase in the vascular endothelial wall preventing the synthesis of prostacyclin, a potent vasodilator and inhibitor of platelet aggregation. However, as the endothelial cell is capable of synthesising new cyclo-oxygenase, whereas the platelet is not, the effect on thromboxane is longer lasting.

THERAPEUTIC INDICATION:

TORPLAT A is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with acute coronary syndromes (ACS) including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG) where both Ticagrelor and Aspirin are required.

DOSAGE AND ADMINISTRATION:

Dosage: The recommended dose is one tablet of (A) Ticagrelor 90mg, one tablet of (B) Aspirin 75 mg shall be administered at day time and one tablet of (A) Ticagrelor 90mg shall be administered at night time. (See blister for the dosage directions)

Method of administration: For oral use. Ticagrelor can be administered with or without food. For patients who are unable to swallow tablets whole, Ticagrelor tablets can be crushed, mixed with water and drunk. The mixture can also be administered via a nasogastric tube (CH8 or greater).

Aspirin tablets 75mg is for oral administration to adults only. Take the tablet with water, do not cut, chew or crush the tablet. Swallow whole.

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 • Haemorrhagic diathesis; coagulation disorders such as haemophilia and thrombocytopenia or concurrent anticoagulant therapy • Severe renal impairment • Patients who are suffering from gout

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. **Hepatic impairment** Use of ticagrelor is contraindicated in patients with severe hepatic impairment. **Bradyarrhythmias** Ticagrelor can cause ventricular pauses. Bradyarrhythmias including AV block have been reported in the postmarketing setting. **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. **Hypersensitivity reactions:** Aspirin may also precipitate bronchospasm or induce attacks of asthma in susceptible subjects or promote other hypersensitivity reactions. **Serious skin reactions**, including Steven-Johnsons syndrome, have rarely been reported in association with the use of acetylsalicylic acid. **Pregnancy and breast feeding:** Aspirin 75 mg tablets is not recommended during menorrhagia where it may increase menstrual bleeding. Aspirin should be avoided in late pregnancy and generally during breast feeding.

DRUG INTERACTION: Strong CYP3A Inhibitors – Strong CYP3A inhibitors substantially increase ticagrelor exposure and so increase the risk of dyspnea, bleeding, and other adverse events. Avoid use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin).

Strong CYP3A Inducers - Strong CYP3A inducers substantially reduce ticagrelor exposure and so decrease the efficacy of ticagrelor. Avoid use with strong inducers of CYP3A (e.g., rifampin, phenytoin, carbamazepine and phenobarbital).

Ticagrelor inhibits the P-glycoprotein transporter; monitor digoxin levels with initiation of or change in Ticagrelor therapy.

Methotrexate (used at doses >15 mg/week):

The combined drugs, methotrexate and acetylsalicylic acid, enhance haematological toxicity of methotrexate due to the decreased renal clearance of methotrexate by acetylsalicylic acid.

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, tinnitus, Menorrhagia, Steven-Johnsons syndrome, Lyells syndrome.

STORAGE: Store protected from moisture at a temperature not exceeding 30°C. Keep out of reach of children.

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IN/ TORPLAT A COPACK 90 & 75 MG/MAR-21/01 /ABPI
(Additional information is available on request)