PRAX

For the use of a Registered Medical Practitioner

Abbreviated Prescribing information for PRAX (Prasugrel Hydrochloride Tablets I.P.)

[Please refer the complete prescribing infonnation for details: www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Prasugrel is an inhibitor of platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y12 class of ADP receptors on platelets. Since platelets participate in the initiation and/or evolution of thrombotic complications of atherosclerotic disease, inhibition of platelet function can result in the reduction of the rate of cardiovascular events such as death, myocardial infarction, or stroke.

INDICATION: Prasugrel Hydrochloride Tablets is indicated To reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as a follows:Patients With Unstable Angina (UA) Or non-st-elevation Myocardial Infaraction (NSTEMI). Patients With st-elevation Myocardial Infaraction (STEMI) When Managed with Primary or Delayed PCI.

DOSAGE AND ADMINISTRATION: Prasugrel Hydrochloride Film coated tablet 5, 10 mg.

CONTRAINDTCATTONS: Hypersensitivity to the active substance or to any of the excipients. Active pathological bleeding. History of stroke or transient ischaemic attack (TIA). Severe hepatic impairment (Child Pugh class C).

WARNINGS & PRECAUTIONS: *Bleeding risk:* increased risk of bleeding; anaemia; thrombocytopaenia; a history of pathological intracranial findings. Patients with acute coronary syndromes undergoing PCI treated with Efient and ASA showed an increased risk of major and minor bleeding according to the TIMI classification system. Therefore, the use of Efient in patients at increased risk of bleeding should only be considered when the benefits in terms of prevention of ischaemic events are deemed to outweigh the risk of serious bleedings. This concern applies especially to patients: • ≥ 75 years of age (see below). With a propensity to bleed (e.g. due to recent trauma, recent surgery, recent or recurrent gastrointestinal bleeding, or active peptic ulcer disease) with body weight < 60 kg (see sections 4.2 and 4.8). In these patients the 10 mg maintenance dose is not recommended. A 5 mg maintenance dose should be used. With concomitant administration of medicinal products that may increase the risk of bleeding, including oral anticoagulants, clopidogrel, non-steroidal anti-inflammatory drugs (NSAIDs), and fibrinolytics. *Bleeding Risk Associated with Timing of Loading Dose in NSTEMI:* In a clinical trial of NSTEMI patients (the ACCOAST study), where patients were scheduled to undergo coronary angiography within 2 to 48 hours after randomization, a prasugrel loading dose given on average 4 hours prior to coronary angiography increased the risk of major and minor peri-procedural bleeding compared with a prasugrel loading dose at the time of PCI. Therefore, in UA/NSTEMI patients, where coronary angiography is performed within 48 hours after admission, the loading dose should be given at the time of PCI. *Surgery:* Patients should be advised to inform physicians and dentists that they are taking prasugrel before any surgery is scheduled and before any new medicinal product is taken. If a patient is to undergo elective surgery, and an antiplatelet effect is not desired, Efient should be discontinued at least 7 days prior to surgery. Increased frequency (3-fold) and severity of bleeding may occur in patients undergoing CABG surgery within 7 days of discontinuation of prasugrel (see section 4.8). The benefits and risks of prasugrel should be carefully considered in patients in whom the coronary anatomy has not been defined and urgent CABG is a possibility. *Hypersensitivity including angioedema:* Hypersensitivity reactions including angioedema have been reported in patients receiving prasugrel, including in patients with a history of hypersensitivity reaction to clopidogrel. *Thrombotic Thrombocytopaenic Purpura (TTP):* TTP has been reported with the use of prasugrel. TTP is a serious condition and requires prompt

treatment. *Lactose and sodium:* Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. *Morphine and other opioids:* Reduced prasugrel efficacy has been seen in patient's co-administered prasugrel and morphine.

DRUG INTERACTIONS: *Warfarin and Non-steroidal anti-inflammatory drugs (NSAIDs):* has potential for incresed risk of bleeding. Efient can be concomitantly administered with medicinal products metabolised by cytochrome P450 enzymes (including statins), or medicinal products that are inducers or inhibitors of cytochrome P450 enzymes. Efient can also be concomitantly administered with ASA, heparin, digoxin, and medicinal products that elevate gastric pH, including proton pump inhibitors and H_2 blockers. Effects of other medicinal products on Efient: *Acetylsalicylic acid*, *Statins, Medicinal products that elevate gastric pH, Inhibitors of CYP3A, Inducers of cytochromes P450: Morphine and other opioids etc*.Effects of Efient on other medicinal products: *Digoxin*: Prasugrel has no clinically significant effect on the pharmacokinetics of digoxin. *Medicinal products metabolised by CYP2C9*: Prasugrel did not inhibit CYP2C9, as it did not affect the pharmacokinetics of S-warfarin. *Medicinal products metabolised by CYP2B6*: Prasugrel is a weak inhibitor of CYP2B6. In healthy subjects, prasugrel decreased exposure to hydroxybupropion, a CYP2B6-mediated metabolite of bupropion, by 23%.

ADVERSE REACTIONS: ***Blood and Lymphatic System disorders:*** Anaemia, Thrombocytopaenia, Thrombotic thrombocytopaenic purpura (TTP). ***Immune system disorders*****:** Hypersensitivity including angioedema. ***Eye disorders*****:** Eye haemorrhage. ***Vascular Disorders*****:** Haematoma. ***Respiratory, thoracic and mediastinal disorders*****:** Epistaxis, Haemoptysis. ***Gastrointestinal disorders*****:** Gastrointestinal haemorrhage, Retroperitoneal haemorrhage, Rectal haemorrhage, Haematochezia, Gingival bleeding. ***Skin and subcutaneous tissue disorders*****:** Rash, Ecchymosis. ***Renal and urinary disorders*****:** Haematuria. ***General disorders and administration site conditions*****:** Vessel puncture site haematoma, Puncture site haemorrhage. ***Injury, poisoning and procedural complications*****:** Contusion, Post-procedural haemorrhage, subcutaneous haematoma.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)