

## PRAX A 75

For the use of a Registered Medical Practitioner

### Abbreviated Prescribing information for PRAX A (Prasugrel Hydrochloride 10mg And Aspirin 75mg Capsules)

[Please refer the complete prescribing information for details: [www.torrentpharma.com](http://www.torrentpharma.com)]

#### PHARMACOLOGICAL PROPERTIES:

**Mechanism of Action:** Prasugrel, a thienopyridine class inhibitor of platelet activation and aggregation mediated by the P2Y12 ADP receptor. Aspirin is analgesic, antiinflammatory, antipyretic and an inhibitor of platelet aggregation.

**DOSAGE AND ADMINISTRATION:** Recommended dose once daily Prax A 75 for maintenance treatment.

**CONTRAINDICATIONS: Prasugrel:** Active pathological bleeding, History of stroke or transient ischaemic attack (TTA), Severe hepatic impairment (Child-Pugh class C), Patient >75 years of age, Patient < 60 kg. **Aspirin:** Nasal polyps associated with asthma, Active peptic ulceration, Haemophilia or other haemorrhagic disorder (including thrombocytopenia) as there is an increased risk of bleeding, Concurrent anticoagulant therapy, severe hepatic and renal impairment, severe cardiac failure, Third trimester of pregnancy and Children under 16 years. Hypersensitivity to the active substance or to any of the excipients. Known hypersensitivity to other salicylates or non-steroidal anti-inflammatory drugs.

**WARNINGS & PRECAUTIONS: Prasugrel:** Bleeding risk, Surgery, Hypersensitivity including angioedema and hypersensitivity including angioedema, patients with rare hereditary problems of galactose intolerance should not take Prasugrel. **Aspirin:** Allergic disease, anaemia, asthma, cardiac failure, dehydration, glucose-6-phosphate dehydrogenase deficiency, gout, hepatic function impairment, renal function impairment, systemic lupus erythematosus, thyrotoxicosis, long term use in elderly patients and vaccine recipients. Vaccine recipients should avoid use of salicylates for 6 weeks after varicella vaccination.

**DRUG INTERACTIONS: Prasugrel:** Warfarin, heparin, statins, medicinal products that elevate gastric pH, inhibitors of CYP3A, inducers of cytochromes P450 and digoxin. **Aspirin:** Alcohol, analgesics, alkalizers of urine, anticoagulants, anti-epileptic drugs, corticosteroids, dipyridamole, diuretics, hypoglycaemic agents, methotrexate, metoclopramide and domperidone, mifepristone, ototoxic medicine, uricosurics, ACE inhibitors, calcium-channel blockers, SSRIs, varicella vaccine and Ginkgo Biloba.

**ADVERSE REACTIONS: Prasugrel:** Bleeding, Hypertension, Hypercholesterolemia/Hyperlipidemia, Headache, Back pain, Dyspnea, Nausea, Dizziness, Cough, Hypotension, Fatigue, Non-cardiac chest pain, Atrial fibrillation, Bradycardia, Leukopenia, Rash, Pyrexia, Peripheral edema, Pain in extremity, Diarrhea, Hypersensitivity reactions including anaphylaxis, Thrombocytopenia, Thrombotic thrombocytopenic purpura, Anaemia, Haematoma, Epistaxis, Haemoptysis, Eye haemorrhage, Retroperitoneal haemorrhage, Rectal haemorrhage, Haematochezia, Gingival bleeding, Gastrointestinal haemorrhage, Ecchymosis, Haematuria, Vessel puncture site haematoma, Puncture site haemorrhage, Contusion, Post-procedural haemorrhage, Subcutaneous haematoma. **Aspirin:** anaemia, hypoprothrombinaemia, thrombocytopenia, aplastic anaemia, pancytopenia, prolonged bleeding time, occult blood loss, elevated transaminase levels, agranulocytosis, gastrointestinal bleeding, erosions, perforations or ulceration, gastrointestinal irritation, hepatitis, disturbances of renal

function, tinnitus, salicylism, Allergic reactions including rhinitis, urticaria, Stevens-Johnson syndrome, angioneurotic oedema, angio-oedema, asthma, worsening of asthma, bronchospasms.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)