CLODREL PLUS/CLODREL FORTE

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

Abbreviated Prescribing information for CLODREL PLUS/CLODREL FORTE [Clopidogrel and Aspirin Tablets I.P]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Clopidogrel:*** The active metabolite of clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet P2Y12 receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. ***Aspirin:*** Acetylsalicylic acid inhibits platelet aggregation by irreversible inhibition of prostaglandin cyclo-oxygenase and thus inhibits the generation of thromboxane A2, an inducer of platelet aggregation and vasoconstriction.

INDICATIONS: It is indicated for the treatment of angina, myocardial infarction, and stroke.

DOSAGE AND ADMINISTRATION: CLODREL PLUS should be given as a single daily 75 mg/75 mg dose. CLODREL FORTE should be given as a single daily 75 mg/150 mg dose. If dose is missed Within less than 12 hours after regular scheduled time: patients should take the dose immediately and then take the next dose at the regular scheduled time. For more than 12 hours: patients should take the next dose at the regular scheduled time and should not double the dose. The product is for oral use. It may be given with or without food.

CONTRAINDICATION: •Hypersensitivity to clopidogrel, acetylsalicylic acid or to any of the ingredients of CLOPIDOGREL ASPIRIN 75/75 mg PD. •Active or history of pathological bleeding such as recurrent peptic ulcer/haemorrhage/perforations or intracranial haemorrhage. •Severe hepatic impairment. •Thrombocytopenia and platelet dysfunction • Patients with severe renal impairment • Patients with heart failure •Pregnancy and lactation •(PUBs) related to previous NSAIDs.

WARNINGS & PRECAUTIONS: In patients with recent transient ischaemic attack or stroke who are at high risk of recurrent ischaemic events, the combination of aspirin and clopidogrel has been shown to increase major bleeding. Patients with a confirmed diagnosis of acquired haemophilia should be managed and treated by specialists, and CLOPIDOGREL ASPIRIN 75/75 mg PD should be discontinued. Caution is required in patients with a history of hypertension and/or heart failure. Caution is required when administering to patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions associated with bleeding diathesis as well as in patients receiving treatment with other NSAIDs, heparin, glycoprotein IIb/IIIa inhibitors, selective serotonin reuptake inhibitors (SSRIs), or CYP2C19 strong inducers, or thrombolytics. The concomitant administration of CLOPIDOGREL ASPIRIN 75/75 mg PD with oral anticoagulants is not recommended. Spinal and epidural anaesthesia should not be administered or for 7 days thereafter. In patients with a history of gastrointestinal disease, peptic ulcer, gastroduodenal haemorrhage or minor upper gastrointestinal symptoms, it should be used with caution as the condition may be exacerbated. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens Johnson syndrome, and toxic epidermal necrolysis have been reported.

DRUG INTERACTIONS: In patients concomitantly receiving nicorandil and NSAIDs, there is an increased risk for severe complications such as gastrointestinal ulceration, perforation, and haemorrhage. Concomitant administration of warfarin with CLOPIDOGREL ASPIRIN 75/75 mg PD is not recommended due to the increased risk of bleeding. the concomitant use of NSAIDs, including Cox-2 inhibitors, is not recommended. The concomitant administration of SSRIs with clopidogrel should be undertaken with caution as SSRIs affect platelet activation and increase the risk of bleeding. Caution is required because ASA may inhibit the effect of uricosuric agents through competitive elimination of uric acid. Metamizole may reduce the effect of ASA on platelet aggregation when taken concomitantly. Use

of two or more NSAIDs concomitantly could result in an increase in side effects. Increased risk of gastrointestinal perforation, ulceration, or bleeding (PUBs) with corticosteroids. Increased risk of gastrointestinal bleeding with SSRI. Due to the increased risk of metabolic acidosis, caution is recommended when co administering salicylates with acetazolamide. Thyroid hormone levels should be monitored as salicylates, specifically at doses greater than 2,0 g/day, lead to an initial transient increase in free thyroid hormones, followed by an overall decrease in total thyroid hormone levels. Concomitant administration of tenofovir disoproxil fumarate and NSAIDs may increase the risk of renal failure. Alcohol, when taken with ASA, may increase the risk of gastrointestinal injury.

ADVERSE REACTIONS: The reported side effects include thrombocytopenia, increased bleeding time, leucopenia, eosinophilia, neutropenia, aplastic anaemia, intracranial bleeding, headache, dizziness, paraesthesia, eye bleeding, vertigo, haematoma, epistaxis, dyspepsia, abdominal pain, diarrhoea, nausea, gastritis, flatulence, constipation, vomiting, gastric ulcer, duodenal ulcer, bruising, rash, pruritus, purpura, haematuria, bleeding at puncture site, serious bleeding (skin, musculoskeletal, eye, respiratory tract, operative wound), haemorrhage with fatal outcome, acquired haemophilia A, thrombotic thrombocytopenic purpura, pancytopenia, agranulocytosis, anaemia, anaphylactoid reactions, serum sickness, hypersensitivity, insulin autoimmune syndrome, Kounis syndrome, confusion, hallucinations, taste disturbances, ageusia, vasculitis, hypotension, bronchospasm, interstitial pneumonitis, eosinophilic pneumonia, colitis, stomatitis, pancreatitis, acute liver failure, hepatitis, abnormal liver function, maculopapular rash, urticaria, angioedema, bullous dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug-induced hypersensitivity syndrome, eczema, lichen planus, arthritis, arthralgia, myalgia, glomerulonephritis, increased blood creatinine, gynaecomastia, fever, haemolytic anaemia, bicytopenia, bone marrow failure, hypoglycaemia, gout, hearing loss, tinnitus, hypertension, cardiac failure, non-cardiogenic pulmonary oedema, gastro-duodenal ulcer, perforations, oesophagitis, erosive gastritis, erosive duodenitis, melaena, haematemesis, ulcerative stomatitis, exacerbation of Crohn’s disease, liver injury, chronic hepatitis, fixed eruption, renal failure, acute renal impairment, and oedema.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/CLODREL PLUS 75/75 mg and CLODREL FORTE 75/150 mg/MAR 2026/01/ABPI

(Additional information is available on request)