

CHYMORAL FORTE / CHYMORAL FORTE – DS

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

Abbreviated Prescribing information for CHYMORAL FORTE / CHYMORAL FORTE – DS [Trypsin-Chymotrypsin Tablets]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Trypsin: A proteolytic enzyme crystallised from an extract of the pancreas of healthy bovine or porcine animals, or both. It contains not less than 2500 USP units in each mg, calculated on the dried basis. A white to yellowish-white, odourless, crystalline or amorphous powder. Store in airtight containers at temperature not exceeding 40°C. **Chymotrypsin:** A proteolytic enzyme crystallised from an extract of the pancreas gland of the ox, *Bos taurus* (Bovidae). It contains not less than 1000 USP units in each mg, calculated on the dried basis. A white to yellowish-white, crystalline or amorphous, odourless powder. An amount equivalent to 100 000 USP units is soluble in 10 mL of water and in 10 mL of sodium chloride 0.9%. Store in airtight containers at a temperature not exceeding 40°C.

INDICATIONS: (a) Acute or chronic osteoarthritis, rheumatoid arthritis and spondyloarthritis, spondylosis and other ortho-degenerative disorders, pain management. (b) Surgery: Post-operative wounds, Oedema and Haematoma, Prevention of inflammation of the stitching. (c) Gynecology: Pelvic Inflammatory Disease, Caesarean section, Episiotomy and Hysterectomy. (d) Dentistry: Tooth Extraction, Peri apical abscess, Maxillofacial surgery. (e) Ophthalmology: Ocular Trauma such as Macular edema, Black eye, Hyphema, Uveal tract inflammation, Subconjunctival hemorrhage, (f) ENT: Auricular Septal hematoma, Nasal fractures, Parapharyngeal abscess. (g) Orthopedics: Post-traumatic edema, soft tissue injury, Fractures & dislocation, Sports injury, Sprains & Strains, Intervertebral disc herniation (sciatica or PID), (h) Ophthalmology: Ocular Trauma such as Macular oedema, Black eye, Hyphema, Uveal tract inflammation, Subconjunctival haemorrhage, Extra-ocular trauma.

DOSAGE AND ADMINISTRATION: Dose: The dose and dose frequency of Trypsin-Chymotrypsin will be decided under the supervision of qualified physician. **Method of administration:** As directed by the Physician

CONTRAINDICATION: (a) Adjunctive therapy in management of inflammatory edema due to injury, surgery, infection or dental procedures. (b) Hypersensitivity to Trypsin-Chymotrypsin ingredients or enzymes. (c) Trypsin-Chymotrypsin is contraindicated in patients with severe liver, kidney impairment, peptic ulcer, high vitreous pressure, and hypersensitivity.

WARNINGS & PRECAUTIONS: Chymotrypsin is safe when used in the eye by a healthcare professional. It can cause side effects when used in the eye, including an increase in pressure in the eye and other eye conditions such as uveitis, paralysis of the iris, and keratitis. Chymotrypsin also seems to be safe for most people when taken by mouth to reduce redness and swelling following surgery or injury, and when applied directly to the skin for burns. Rarely, chymotrypsin might cause an allergic reaction when taken by mouth. Symptoms include itching, shortness of breath, swelling of the lips or throat, shock, loss of consciousness, and death. Not be employed in patients with severe hepatic insufficiency or renal damage or irregularities of blood clotting mechanism. Trypsin and Chymotrypsin should not be employed in patients with severe hepatic insufficiency and should be given cautiously to patient with renal damage or irregularities of blood clotting mechanism. It should be used for a week after pulmonary hemorrhage. After many years of widespread clinical use, there is no reason to believe that Trypsin and Chymotrypsin is or may be teratogenic in humans. However, it its sound medical principle to exercise precaution in prescribing any medications during the first three months of pregnancy. Severe hepatic or renal disease. To be used with caution during Lactation, or in the elderly, children, pregnancy (use only, if clearly indicated) and patients with irregularities of blood clotting

mechanism.

DRUG INTERACTIONS: When certain medications are taken together with Trypsin drug interactions could occur that may affect the efficacy of the medicines. It can even increase your risk for side effects. Trypsin can interact with other medicines such as vitamins, minerals, herbal products, and drugs prescribed by other doctors resulting in side effects or altered effectiveness of Trypsin. **Drug- drug interactions:** Systemic proteases may increase the effectiveness of herbal supplements. Chymotrypsin is also known to interact with alcohol. **Antibiotics:** Administration of Trypsin-Chymotrypsin combination (intramuscularly) has been found to increase in the levels of the orally administered semi synthetic penicillin antibiotics in the blood serum and organs of the rats. Chymotrypsin is known to interact with chloramphenicol. **Anticoagulants:** Trypsin-Chymotrypsin combination should not be administered concurrently with anticoagulants such as Coumadin, Heparin and clopidogrel.

ADVERSE REACTIONS: Hepatic damage and necrosis may precipitate arrhythmias, shivering during recovery. Rarely, chymotrypsin might cause an allergic reaction when taken by mouth. Symptoms include itching, shortness of breath, swelling of the lips or throat, shock, loss of consciousness, and death.

MARKETED BY:

TORRENT
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)