SWISS PHARMA

Trypsin - Chymotrypsin Tablets

Summary Product Characteristics (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Trypsin - Chymotrypsin Tablets, 50000 Armour Units of enzymatic activity, Enteric Coated Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric coated tablet contains
50,000 Armour units of enzymatic activity.
Supplied by a purified concentrate which has
Specific trypsin and chymotrypsin activity in a
Ratio of Approximately 6:1

Kindly refer section 6.1 for full list of excipients.

3. PHARMACEUTICAL FORM

Enteric coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Resolving oedema and modulating inflammation associated with various conditions such as accidental and surgical trauma.
Assists in episiotomies.
Neuralgia with pain radiating into the buttock & lower limb most commonly due to lntervertebral disk herniation.
Inflammation of a vein associated with thrombus formation known as thrombophlebitis.
Gynecological surgery such as vasectomy & caesarean.
Bronchitis for reduction in viscosity of mucus & sputum formation.
Dentistry, specially for tooth extraction. periapical abscess & maxilofacial surgery.
Fractures & dislocation.
Sprains & strains.
Ocular trauma such as macular oedema, black eye, hyphema, uveal tract inflammation, sub-conjunctival hemorrhage, extra ocular trauma.
ENT such as nasal fractures. para-pharyngeal abscess.
Enhancement of antibiotic concentration at the site of infection and prevention of formation of adhesions.

4.2 Posology and method of administration

Tablets for oral administration.
Administered 1 tablet 4 times a day. The tablet must be taken half an hour before meals or as directed by the physician.

Method of administration
Route of administration is oral.

4.3 Contraindications
Contraindicated in patients with severe liver problems, kidney impairment, peptic ulcer, high vitreous pressure. Hypersensitivity to the ingredients of TRYPSIN - CHYMOTRYPSIN TABLETS

4.4 Special warnings and precautions for use
Warn your doctor if you are taking other medications, have a chronic disease, a metabolic disorder, or if you are hypersensitive to medicines or have had allergic reactions to some of them. Do not take TRYPSIN - CHYMOTRYPSIN TABLETS if you are hypersensitive to the constituent components of the medicine. In the case of bacterial infection, the proven or suspected (e.g., septicemia, severe generalized or localized - local infection), the TRYPSIN - CHYMOTRYPSIN TABLETS can applied only with appropriate antibiotic therapy. Although there is no compelling evidence that the composition made in this way affect the blood coagulation process, however, it should be applied cautiously in patients with blood coagulation disorders, in cases of severe liver damage and/or kidney disease and in individuals who have a history of recorded allergic reactions to medicines and/or foods.
In patients with history of sensitivity of enzymes or other drugs caution should be exercised.
Safety has not been established in pregnancy and children.
It should be used for a week after pulmonary hemorrhage.
In hepatic & renal insufficiency.
Patients with known sensitivity to enzymes.
Take precautions during the first three months of pregnancy.

4.5 Interaction with other medicinal products and other forms of interaction
We currently have no information for trypsin-chymotrypsin Interactions

4.6 Pregnancy and Lactation
After many years of wide spread clinical use there is no reason to believe that proteolytic enzyme is or may be teratogenic in humans. However, it is sound medical principle to exercise precautions in prescribing any medication during the first three months of pregnancy.
Not enough is known about the use of trypsin-chymotrypsin during pregnancy and breast-feeding. Stay on the safe side and avoid use.

4.7 Effects on ability to drive and use machines
None reported

4.8 Undesirable effects
Rarely TRYPSIN - CHYMOTRYPSIN TABLETS 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.
Occasional gastric disturbance may also occur.

It 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 not be used for it week after pulmonary haemorrhage.
Hepatic damage & necrosis may precipitate arrhythmias, shivering during recovery.
Trypsin can cause side effects such as pain and burning, difficulty breathing
Swelling of your face, lips, tongue, or throat.
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.

4.9 Overdose
Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Trypsin Chymotrypsin, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Proteolytic Action: Chymosin/Chymosin Forte causes proteolysis by breaking down proteins into peptones and into smaller fragments called amino acids. The peptones and amino acids are absorbed by the cells of the small walls.
Fibrinoytic Action: It facilitates the action of fibrolytic agent “PLASMIN” that restores circulation, resolving edema and hematoma. It promotes phagocytosis to remove debris.
Vascular Response Modulator: the drug increases the levels of APR which minimizes the necrotic damage and scarring.
Modulation of inflammation: the drug reduces the proinflammatory mediators. The fibrin blocked microcirculation could be cleared earlier by the administration of the enzymes and hence the inflammation resolves quicker and healing commences at an early stage..

5.2 Pharmacokinetic properties
Proteolytic enzymes are large protein molecules and there exist a doubt whether they will be absorbed in an active form from the gastrointestinal tract. To overcome their destruction in stomach by hydrolysis, these tablets are given in enteric coated dosage form.
There are very few reports of well-controlled randomized clinical trials. Thus, anti-inflammatory activity after oral administration has not been convincingly demonstrated. Most of the clinical data are not adequately controlled, and is based on the subjective observations.
Very little is known about their mechanism of action.
No clinical data is available on the fate and excretion of proteolytic enzymes.
They are released and absorbed in the small intestine, when given in enteric coated fThey pass the destructive activity of the acid pepsin of the stomach.
The onset of action is after half an hour.

5.3 Preclinical safety data
No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch
Lactose
Povidone K30
Purified Water
Magnesium Stearate
Colloidal Anhydrous silica
Ready Enteric Coating White Powder
Isopropyl Alcohol
Methylene Chloride
Sucrose
Gelatin
Talcum
Idacol Ponceau 4r Supra Colour
Beeswax
Carnauba Wax
Gum Acacia
Titanium Dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at temperature below 30°C. Protect from light.
Keep medicines out of reach of children.

6.5 Nature and contents of container

Jar Pack

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORISATION HOLDER
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