BRAND NAME:	
GENERIC NAME:	**TRYPSIN - CHYMOTRYPSIN TABLETS**

1.3 PRODUCT INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of drug product

TRYPSIN-CHYMOTRYPSIN TABLETS

1.1 (Trade) name of product

TRYPSIN - CHYMOTRYPSIN TABLETS

1.2 Strength

Each Enteric Coated Tablet Contains:

Trypsin-Chymotrypsin Eq. to 50000 armour units of enzymatic activities

1.3 Pharmaceutical Dosage Form

Tablets for oral administration

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2. QUALITATIVE & QUANTITATIVE COMPOSITION 2.1

Qualitative Declaration

Each Enteric Coated Tablet Contains:

Trypsin-Chymotrypsin Eq. to 50000 armour units of enzymatic activities

Excipients.....q.s.

Colour : Permitted colour

2.2 Quantitative Declaration

Batch Formula:

Batch Size: 1, 00,000 Tablets

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3. PHARMACEUTICAL DOSAGE FORM

Tablet for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Trypsin + Chymotrypsin, a combination of therapeutic enzymes, are prescribed for the treatment of active inflammatory edema associated with post-surgical wounds, traumatic injuries, pelvic inflammatory disorders and sciatica.

Trypsin + Chymotrypsin are also prescribed for rhinitis, sinusitis, as an additive for antibiotic therapy, to lower mucus viscosity (mucovisciodosis) and phlegm in bronchitis.

Trypsin-chymotrypsin tablets are indicated in post-operative wounds, oedema andhaematoma, prevention of inflammation of the surgical stitches, pelvic inflammatory disease, caesarean section, episiotomy, abdominal hysterectomy, tooth extraction, peri-apical abscess, maxillofacial surgery, post-traumatic oedema, soft tissue injury, fractures and dislocation, sports injuries, and sprains andstrains. Treatment should begin as soon as possible after injury occurs.

4.2 Posology and Method of Administration

One tablet, four times a day,half an hour before meals or as directed by the physician. The tablet must be swallowed whole to preserve the enteric coating.

Trypsin-Chymotrypsin tablets taken to enhance digestion are usually taken just before, during, or just after meals, or before going to bed at night. For inflammatory or chronic condition, tablets should be taken on an empty stomach, either 1 hour before meals or at least 2 hours after meals. When tablets are taken for inflammatory condition, some improvement may be noted within 3 - 7 day. Those with chronic condition such as arthritis may require 1 - 3 months or more to notice a change in conditions. To reduce tissue damage in burn patients, 4 tablets four times daily for 10 days are advisable.

4.3 Contraindications

Hypersensitivity to Trypsin Chymotrypsin is a contraindication. In addition, Trypsin Chymotrypsin should not be used if you have the following conditions:

Breastfeeding

Fresh blood clots

Hypersensitivity

Pregnant

4.4 Special Warnings and Precautions for Use

In patients with history of sensitivity of enzymes or other drugs caution should be exercised. Safety has not been established in pregnancy and children.

General

- 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 to be usedin patients with severe hepatic impairmentor renal damage or irregularities of the blood clotting mechanism.

4.5 Interaction with Other Drugs, Other Forms of Interactions

If you use other drugs or over the counter products at the same time, the effects of Trypsin Chymotrypsin may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Trypsin Chymotrypsin may interact with the following drugs and products:

Alcohol

Chloramphenicol

are contraindicated in patients with severe liver problems, kidney impairment, peptic ulcer, high vitreous pressure, and hypersensitivity.

- Hypersensitivity to the ingredients of TRYPSIN - CHYMOTRYPSIN TABLETS.
- TRYPSIN - CHYMOTRYPSIN TABLETS

- Herbal Supplements/Alcohol

  Systemic proteases may increase the effectiveness of herbal supplements. Chymotrypsin is also known to interact with alcohol.
- Antibiotics

  Administration of the trypsin-chymotrypsin combination (intramuscularly) has been found to increase the levels of orally administered semi-synthetic penicillin antibiotics in the blood serum and organs of rats.
- Chymotrypsin is known to interact with chloramphenicol.
- Anticoagulants

  The trypsin-chymotrypsin combination should not be administered concurrently with anticoagulants such as coumadin, heparin and clopidogrel.

4.6 Pregnancy and Lactation

Pregnancy

Not enough is known about the use of trypsin and chymotrypsin during pregnancy.

Lactation

Not enough is known about the use of trypsin and chymotrypsin during breastfeeding.

4.7 Effects on ability to drive and operate machine

No data available.

4.8 Undesirable effects

Generally, it is well tolerated. However, certain effects can be seen, occasional gastric disturbance may occur and increased intraocular pressure, corneal edema, striation and uveitis following ophthalmic use.

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.

Occasional gastric disturbance may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard

4.9 Overdose

No data available

5. Pharmacological properties

5.1 Pharmacodynamic properties

The cells in the pancreas synthesize and produce digestive enzymes that breakdown fats (lipases), starches (amylases) and proteins (proteases). Pancreatic proteases can be divided into several families of enzymes that differ in structure and catalytic effect in how they interact with the peptide bonds of proteins. Trypsin and Chymotrypsin are two types of proteases originally synthesized in the pancreas in the inactive form of zymogen precursors (trypsinogen and chymotrypsinogen) for the purpose of stopping unnecessary cellular activity and controlling when and where enzyme activity occurs. Zymogens are then carried either into the bloodstream or the intestines where they are excreted or are converted by the process of proteolysis into the active enzymes that aid digestion. When taking the trypsin-chymotrypsin combination, the active proteolytic enzymes are being ingested and used in addition to the inactive forms the body naturally produces. Trypsin and chymotrypsin give the body the extra boost it might need for smoother digestion of proteins as well as for reducing inflammation and fighting infection.

Fibrinolytic Activity

When fibrin clots have stopped bleeding, the body's own fibrinolytic agent, plasmin, breaks the fibrin barrier. The liver, in response to trauma, releases acute-phase reactants(APRs) that inhibit plasmin (and its fibrinolytic action). Chymotrypsin and trypsin together break down the fibrin barrier, thus improving and restoring circulation, resolving oedema, haematoma and pain, promoting phagocytosis to remove the debris, and accelerate recovery.

There are reports suggesting that the chymotrypsin-trypsin combination helps modulate the process of inflammation. Thus, the trypsin-chymotrypsin combination reduces the pro-inflammatory mediators and fastens the healing process.

Smoothens the Process of Digestion

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Trypsin helps to break down large protein molecules by cutting protein chains at specific sites. The large protein molecule is actually a chain of smaller units called amino acids,which are linked, end-to-end, in chains of hundreds. There are 20 different amino acids from which these protein chains are made. The specific site along the protein chain where trypsin is active is one with the amino acids, lysine and arginine, which are two of the smaller amino acids.

The enzyme, chymotrypsin, also cuts the larger protein chain, but at sites that are different from where trypsin cuts it. Chymotrypsin makes its cut at positions along the protein chain that contain very large amino acids such as phenylalanine, tyrosine and tryptophan. Otherwise, it is very similar to trypsin.

In some individuals, the production of these digestive enzymes is deficient, resulting in the inability to completely digest food. This can result in abdominal pain, indigestion, gas and malnutrition. This condition is treatable with trypsin-chymotrypsin enzyme supplements.

5.2 Pharmacokinetic properties

They are released and absorbed in the small intestine, when given in enteric coated form.

They pass the destructive activity of the acid pepsin of the stomach.

The onset of action is after half an hour.

5.3 Pre-clinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Maize starch

Lactose

Poly vinyl Pyrrolidon K-3

Magnesium Stearate

Colloidal Silicon Dioxide

Enteric coating material (ENSOL)

Isopropyl Alcohol

Acetone

Sugar

Gelatin

Talcum

Calcium Carbonate

Colour Ponceu-4R

Bees Wax

Carnanuva Wax

Benzene

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

Keep out of reach of children.

6.5 Nature and contents of container

1 X 10 Tablets packed in Alu-Alu Strip of TRYPSIN - CHYMOTRYPSIN TABLETS

6.6 Special precautions for disposal and other special handling.

Not Applicable

7. Marketing authorisation holder

GENEX LIFE SCIENCES LIMITED,
7 Sapara Williams Street, Industrial Estate, Ikeja, Lagos,
Nigeria

8. Manufacturer
McW Healthcare Pvt Ltd, 286, 287-A, 287-B,
SECTOR-E, INDUSTRIAL AREA SANWAR ROAD,
INDORE (M.P.), INDIA