

1.3.1

Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1.3.1.1 Invented Name of the Medicinal Product

G- TRYP

Trypsin-Chymotrypsin Tablets

1.3.1.2 Strength

Each enteric coated tablet contains

50,000 Armour unit of enzymatic activity.

Supplied by a purified concentrated which has specific trypsin and chymotrypsin activity in a ratio of Approximately 6:1

1.3.1.3 Dosage Form

Oral Solid Dosage Form (Enteric CoatedTablet)

1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric coated tablet contains

50,000 Armour unit of enzymatic activity.

Supplied by a purified concentrated which has specific trypsin and chymotrypsin activity in a ratio of Approximately 6:1

1.3.1.5 PHARMACEUTICAL FORM

Brownish Red coloured round shaped biconvex enteric coated tablet.

1.3.1.6 CLINICAL PARTICULARS

1.3.1.6.1 Therapeutic indications

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 and strains.

Treatment should begin as soon as possible after injury occurs.

1.3.1.6.2 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.

1.3.1.6.3 CONTRAINDICATIONS

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

- Hypersensitivity to the ingredients of G-TRYP.
- G-TRYP Tablets

1.3.1.6.4 WARNING AND PRECAUTIONS

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 used in patients with severe hepatic impairment or renal damage or irregularities of the blood clotting mechanism.

1.3.1.6.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

1.3.1.6.6 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.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No data available

1.3.1.6.8 UNDESIRABLE EFFECTS

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.

1.3.1.6.9 OVERDOSE

No data available.

1.3.1.7 PHARMACOLOGICAL 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

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.

1.3.1.8. PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of excipients

Sr. No.	Name of Ingredients	Specification
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01.	Starch	BP
02.	Lactose	BP
03.	P.V.P.K-30	BP
04.	Purified water	BP
05.	Magnesium Stearate	BP
06.	Fumed Silica	BP
Coating material		
07	Ready Enteric Coating Ponceau4R Powder	BP
08	Isopropyl alcohol	BP
09	Methylene chloride	BP

1.3.1.8.2 Incompatibilities:

None stated.

1.3.1.8.3 Shelf life:

2 years

1.3.1.8.4 Special precautions for storage:

Store below 30⁰ C. Protect from moisture.

1.3.1.8.5 Nature and contents of container:

3 x 10 strip pack.

10 tablets packed in one strip and 3 strips are packed in one carton along with package insert.

1.3.1.8.6 Special precautions for disposal and other Special handling:

No special requirements.

Brand Name: G- TRYP

Generic Name: Trypsin-Chymotrypsin Tablets

Module 1

(Administrative File)

1.3.1.9 Marketed by:

M/S. Greenlife Pharmaceuticals Ltd.,

2, Bank Lane,

Off Town Planning Way,

Ilupeju,

Lagos, Nigeria.

1.3.1.10 Manufactured by:

SWISS PHARMA PVT. LTD.

3709, G.I.D.C., Phase-IV, Vatva,

Ahmedabad-382 445
