1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

1.0 NAME OF THE MEDICINAL PRODUCT

Trypsin/Chymotrypsin Tablet

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Enteric coated tablet contains:

Trypsin-Chymotrypsin (6.1 approx.) Eq. to 50,000

(U.S.P.) unit of proteolytic enzyme activity

Excipients..... Q.S.

Colour: Ponceau 4 R and Sunset Yellow FCF

3.0 PHARMACEUTICAL FORM:

Enteric coated tablet

Red coloured, round shaped, biconvex, enteric coated tablets.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications

Trypsin-Chymotrypsin tablets are indicated in post-operative wounds, oedema and haematoma, 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.

4.2 Posology and method of administration

Posology

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.

Method of administration

Tablets should be swallowed whole with adequate fluids (at least 100ml of water) and should be taken in an upright sitting or standing position.

4.3 Contraindications

Trypsin-Chymotrypsin tablets 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

Erythromycin is contraindicated in patients taking simvastatin, tolterodine, mizolastine, amisulpride, astemizole, terfenadine, domperidone, cisapride or pimozide.

Erythromycin is contraindicated with ergotamine and dihydroergotamine.

4.4 Special warnings and precautions for 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.

4.5 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.

4.6 Fertility, 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 use machines

Not relevant.

4.8 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.

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.

4.9 Overdose

No case of overdose has been reported

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used as Enzymes

ATC code: B06AA04

The cells in the pancreas synthesize and produce digestive enzymes that break down 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.

5.2 Pharmacokinetic properties

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 accelerating 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.

5.3 Preclinical safety data

None Clinical reveal on safety data.

6. Pharmaceutical particulars

6.1 List of excipients

Starch
Micro Crystalline Cellulose Powder
Di Basic Calcium Phosphate
Lactose
Calcium Carbonate
Gelatin
Sodium Methyl Paraben
Sodium Propyl Paraben
P.V.P.K.-30
Sodium Lauryl Sulphate
Purified Water
Talcum
Magnesium stearate
Aerosil
Croscarmellose Sodium
Iso Propyl Alcohol
Methylene Di Chloride
Seal Coat (2%)
Enteric Coat Ready Mix Red (8%)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store Below 30°C in a cool dry & dark place. Protect from light. Keep all medicines out of reach of children.

6.5 Nature and contents of container

10 X 3 X 10 Tablets are packed in Alu-Alu strip, packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

MODULE 1 Administrative and Product Information

TRYPSIN/CHYMOTRYPSIN TABLETS

MODULE 1 Administrative and Product Information

7. Marketing authorisation holder

MOREHOPE PHARMA LTD.,

Lagos, Nigeria.

8. Manufactured By:

Flourish Pharma.,

24 E, GOA-IDC, Daman Industrial Estate,

Daman (U.T.), India.