

**SUMMARY OF PRODUCT
CHARACTERISTICS (SmPC)
FOR DRUG PRODUCTS IN NIGERIA**

**APHAMORAL TABLETS
(Trypsin - Chymotrypsin Tablets)**

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of drug product

Brand Name : APHAMORAL

Generic Name: Trypsin - Chymotrypsin Tablets

Strength

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

Dosage Form

Enteric coated tablets

Rout of administration: Oral

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Each Enteric Coated Tablet Contains:

Trypsin-Chymotrypsin

Eq. to 50000 armour units of enzymatic activities

Colour : Permitted colour

3. PHARMACEUTICAL DOSAGE FORM

Tablet for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Indicated for severe trauma associated with burns, plastic surgery and orthopedic surgery. Trypsin-Chymotrypsin tablets have been used widely, with significant clinical success in the management of major trauma & wound healing and in reducing the healing time. Trypsin-Chymotrypsin is proteolytic enzyme that is used for debridement of wounds. Trypsin is taken by mouth, usually with chymotrypsin, and sometimes with antibacterial or other drugs, for its supposed benefit in relieving oedema and inflammation associated with infection or trauma.

4.2 Posology and Method of Administration

1 tablet, 4 times a day, half an hour before meals or as directed by the physician. The tablet must be swallowed whole with abundant fluids to preserve the enteric coating. Treatment should begin as soon as possible after injury occurs. The therapy is generally continued until the symptoms have subsided. 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

Blood clots

Hypersensitivity

Pregnant women

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

4.5 Interaction with Other Drugs, Other Forms of Interactions

The concomitant administration of Trypsin- Chymotrypsin with antibiotics leads to increased concentration of the antibiotics at their site of activity. Trypsin- Chymotrypsin should not be used together with acetylcysteine, a drug used to thin mucus in the lungs. It should not be used together with anticoagulant (blood thinning) drugs as it increases their effects. Chloramphenicol, a medication used to treat eye infections, may-counteract the effectiveness of chymotrypsin.

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

There do not appear to be any long-term side effects from Trypsin-Chymotrypsin therapy if precautions for its use are followed. Studies have shown that at recommended doses, enzymes cannot be detected in blood analysis after 24-48 hours. Temporary side effects that may occur (but that should disappear when therapy is discontinued or dosage is reduced) include changes in the colour, consistency and odor of the stool. Some individuals may experience gastrointestinal disturbances, such as flatulence, a feeling of fullness, diarrhea, constipation, or nausea. With high doses, minor allergic reactions such as reddening of the skin may occur.

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, starches and proteins. Trypsin and Chymotrypsin are two types of proteases in the serine family. Proteases are being used for pancreatic disease and cancer metastases. Trypsin and Chymotrypsin are originally synthesized in the pancreas in the inactive form of zymogen (proenzyme) precursors for the purpose of stopping unnecessary cellular activity and controlling when and where enzyme activity occurs. Proenzymes are then carried either into the blood stream or the intestine where they are excreted or are converted by process of proteolysis into the active enzymes that aid digestion. Trypsin and Chymotrypsin supplements, the active proteolytic enzymes are being ingested and used in addition to the inactive forms the body naturally produces. Trypsin and Chymotrypsin provides extra boost body might need for smoother digestion of proteins as well as 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 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.

5.3 Pre-clinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Name Of Excipients
Maize starch BP
Lactose BP
Polyvinyl Pyrrolidon K-30 BP
Magnesium Stearate BP
Maize Starch BP
Colloidal Silicon Dioxide BP
Enteric coating material (ENSOL) BP
Isopropyl Alcohol BP
Acetone BP
Sugar BP
Gelatin BP
Talcum BP
Calcium Carbonate BP
Colour Ponceu-4R IH
Bees Wax BP
Carnauva Wax BP
Benzene BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

24 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

Strip pack of 3 X 10 Tablets packed in carton along with pack insert.

6.6 Special precautions for disposal and other special handling.

Not Applicable

7. Marketing authorisation holder
APHANTEE PHARMACEUTICAL NIGERIA LIMITED.
Suit FF 11, First Floor, Pacific complex No. 9, Awaka Road,
Onistha, Anambra State, Nigeria

8. Manufactured by:
McW HEALTHCARE (P) LTD.
286, 287-A, 287-B, Sector – E, Industrial Area,
Sanwer Road, Indore (M.P.), India.

9. NAFDAC REGISTRATION NUMBER(S): A4-9759