1.3 Product Information
1.3.1 Summary of product characteristics (SmPC)
1. Name of the medicinal product: ANIMORAL (Trypsin Chymotrypsin Tablets**)**

2. Qualitative and quantitative composition:
Each Enteric Sugar Coated Tablet Contains:
Trypsin Chymotrypsin 6:1 Equivalent to of Proteolytic Enzyme
Activity USP (50,000 units)
Approved Colour Used. (-)
Excipients (QS)

Excipients with known effect: Lactose Monohydrate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate , Ponceau 4R and Sucrose.

3. Pharmaceutical form: Enteric Sugar Coated Tablet

Description: Red coloured, round shaped, biconvex, enteric sugar coated tablets plain on both sides.

4. Clinical Particulars
4.1 Therapeutic indications:
ANIMORAL (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.

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

4.3 Contraindications
ANIMORAL (Trypsin Chymotrypsin Tablets) are contraindicated in patients with severe liver problems, kidney impairment, peptic ulcer, high vitreous pressure, and hypersensitivity.
Hypersensitivity to the ingredients used in the formulation.

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.
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 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 coumarin, heparin and clopidogrel.

4.6 Pregnancy and Lactation

Pregnancy

Not enough is known about the use of trypsin and chymotrypsin during pregnancy. Thus, is not recommended for pregnant women and nursing mothers. It should be used during pregnancy only when the other alternatives are not available and if the benefit to the mother outweighs the risk to the child.

Lactation

Not enough is known about the use of trypsin and chymotrypsin during breastfeeding. It is recommended to avoid breastfeeding while using this drug.

Fertility

There is no data available on how trypsin and chymotrypsin impact fertility.

4.7 Effects on the ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Trypsin and Chymotrypsin Tablet then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively. Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects.

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.

4.9 Overdoses

Symptoms:

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 **ANIMORAL** Tablet, please go to the emergency department of the closest hospital or nursing home.

Treatment:

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken. No specific antidote exists.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: NSAID
ATC code: M09AB52

Mechanism of action

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. Trypsin and chymotrypsin break down proteins, assisting in the reduction of inflammation and swelling. They can help in the removal of damaged tissue and promote the healing process.

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-toend, 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.

Absorption and Bioavailability
Absorption primarily occurs through the walls of the small intestine, specifically the ileum. The enzymes are absorbed via paracellular diffusion (movement between cells) in their intact, physiologically active form. Their natural proteolytic action is thought to increase tissue permeability, thus facilitating their own absorption. Maximum plasma levels are reached approximately 2-3 hours after oral administration.

Distribution
Once in the bloodstream, the active enzymes rapidly and extensively bind to plasma proteins, primarily alpha-1 antitrypsin and alpha-2 macroglobulin.
This protein-bound fraction is then transported to the site of inflammation or injury where it exerts its therapeutic (fibrinolytic and anti-inflammatory) activity.

Metabolism
The exact metabolic pathways are not fully detailed in the available information, but the metabolites are ultimately cleared from the body. Metabolism is thought to occur primarily in the liver, kidney, and other tissues.

Elimination
Excretion is mainly via the bile and urine. The biological half-life in the plasma is around 18-26 hours, while plasma levels typically return to baseline within 8 hours of administration, which is why multi-day dosing is recommended for therapeutic effect.

Special populations
No relevant data available.

5.3 Preclinical safety Data:
None stated.

6 Pharmaceutical particulars

6.1 List of excipients
Lactose Monohydrate, Maize starch, Microcrystalline Cellulose, Povidone K 30, Colloidal Anhydrous Silica, Sodium Starch Glycolate, Purified Talc, Magnesium stearate, Win coat (Clean Enteric Coat), Calcium Carbonate, Acacia (Gum Acacia), Gelatin (Gelling grade), Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sucrose, Ponceau 4R, Erythrosine Supra, Macrogol 6000.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store in a cool, dry and dark place below 30°C.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Primary packing: 10 Tablets in an ALU-ALU Strip
Secondary packing: 3 Strips are packed in a carton along with leaflet.
Tertiary packing: Such 10 cartons are shrinked. Such 30 Shrinks are packed in a 5 Ply shipper sealed with BOPP tape & strap with strapping roll.

6.6 Special precautions for disposal and other handling

No special requirements.

7 Applicant / Manufacturer

Applicant

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Manufacturer

Manufacturer name and address	**M/s. IMPULSE PHARMA PVT. LTD.** J-201, J-202/1 , MIDC Tarapur, Boisar, Dist. Palghar - 401506, Maharashtra State, India.
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