

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT**

**TIMORAL TABLETS (Trypsin / Chymotrypsin Tablets)**

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Label claim**

Each Enteric Sugar-coated tablet contains:

Trypsin-Chymotrypsin (6:1) eqv. to Proteolytic enzyme activity U.S.P. 50,000 Units

#### **List of Excipients:**

Lactose, Maize Starch, Polyvinyl Pyrrolidone (PVP-K30), Sodium Methyl Paraben and Sodium Propyl Paraben, Microcrystalline Cellulose, Magnesium Stearate, Talcum, Dibutyl Phthalate, Cellulose Acetate Phthalate, Gum Acacia (Micronized), Calcium Carbonate, Methylene Chloride (Dichloro Methane), Polyethylene Glycol 400 (PEG-400), Isopropyl alcohol, Propylene Glycol, Sugar, Talcum, Bees Wax, Carnauba Wax, Colour Ponceau 4 R Supra.

### **3. PHARMACEUTICAL FORM**

Red coloured, round, biconvex, enteric coated, sugar coated tablets with "TIM" printed on one side of each tablet and other side is plain.

### **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**

##### **Dosage and 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.

### **4.3 Contraindications**

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

- Hypersensitivity to the ingredients of TIMORAL Tablets.
- TIMORAL Tablets

### **4.4 Special warnings and precautions for use**

#### **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 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.

### **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**

Use of this medicine may cause drowsiness or dizziness in some patients. It is advised that you do not perform any activities such as driving a vehicle or operating machinery if you experience any of these symptoms during treatment with this medicine.

#### **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 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**

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 Preclinical safety data**

No information available

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose, Maize Starch, Polyvinyl Pyrrolidone (PVP-K30), Sodium Methyl Paraben and Sodium Propyl Paraben, Microcrystalline Cellulose, Magnesium Stearate, Talcum, Dibutyl Phthalate, Cellulose Acetate Phthalate, Gum Acacia (Micronized), Calcium Carbonate, Methylene Chloride (Dichloro Methane), Polyethylene Glycol 400 (PEG-400), Isopropyl alcohol, Propylene Glycol, Sugar, Talcum, Bees Wax, Carnauba Wax, Colour Ponceau 4 R Supra.

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Store below 30°C & keep out of reach of children.

### **6.5 Nature and contents of container**

3 X 10 tablets packed in Strip & 1 x 500 tablets in plastic jar

## **6.6 Instructions for use and handling and disposal**

No special requirements.

## **7. MARKETING AUTHORIZATION HOLDER**

Name : **GREAT TIMEC PHARMA COMPANY LIMITED**

Address : 19B, Niger Bridge head, Housing Estate,  
Fegge, Onitsha, Anambra, Nigeria

### **Name and address of Manufacturer\***

Applicant's Name: **Nem Laboratories Pvt. Ltd.**

Address : 133 Krishna Ind. Estate, Vasai (E)  
Palghar - 401210, Maharashtra-India  
Tel. no. +91(250) 2390002/3

## **8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS**

NAFDAC REGN. NO.: A4-2448

## **9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

9<sup>th</sup> October 2020

## **10. DATE OF REVISION OF THE TEXT**

5<sup>th</sup> August 2021