

SUMMARY PRODUCT CHARACTERISTICS (SPC):

1. Name of the medicinal product: MIMORAL TABLETS (Trypsin - Chymotrypsin Tablets)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Qty / Tablet (mg)	% Overages	Reason for inclusion
Dry Mixing					
1	Lactose	BP	65.00	--	Diluent
2	Maize Starch	BP	37.56	--	Diluent
3	Microcrystalline Cellulose	BP	30.00	--	Filler
Binder Preparation					
4	Povidone	BP	3.00	--	Binder
5	Maize Starch	BP	5.40	--	Binder
6	Purified Water	BP	q.s.	--	Solvent
Lubrication					
7	Trypsin-Chymotrypsin	In-House	18.52	--	Active
8	Colloidal Anhydrous Silica	BP	1.00	--	Glidant
9	Sodium starch Glycolate	BP	3.00	--	Disintegrant
10	Purified Talc	BP	5.00	--	Lubricant
11	Magnesium Stearate	BP	2.50	--	Lubricant
Enteric Coating					
12	Win coat (Clean Enteric Coat)	In-House	15.28	--	Coating Agent
13	Purified Talc	BP	2.50	--	Anti-caking Agent
14	Isopropyl Alcohol	BP	q.s.	--	Solvent
15	Dichloromethane	BP	q.s.	--	Solvent
Sub coating					
Dusting Powder					
16	Calcium Carbonate	BP	3.00	--	Dusting Agent
17	Purified Talc	BP	2.50	--	Dusting Agent
Acacia syrup Preparation					
18	Purified water	BP	q.s.	--	Solvent
19	Acacia (Gum Acacia)	BP	0.75	--	Binder
20	Gelatin	BP	0.200	--	Coating Agent

21	Methyl Paraben	BP	0.150	--	Preservative
22	Propyl Paraben	BP	0.02	--	Preservative
23	Sugar	BP	16.78	--	Sweetening Agent
Pasting Suspension					
24	Purified water	BP	q.s.	--	Solvent
25	Acacia (Gum Acacia)	BP	0.750	--	Binder
26	Gelatin	BP	0.200	--	Coating Agent
27	Sugar	BP	16.63	--	Sweetening Agent
28	Calcium Carbonate	BP	3.00	--	Dusting Agent
29	Purified Talc	BP	2.50	--	Dusting Agent
30	Colour Ponceau 4R Lake	In-House	0.150	--	Colouring Agent
Sugar Syrup Preparation					
31	Purified water	BP	q.s.	--	Solvent
32	Sugar	BP	16.63	--	Sweetening Agent
33	Purified Talc	BP	2.50	--	Dusting Agent
34	Gelatin	BP	0.200	--	Coating Agent
35	Colour Ponceau 4R Lake	In-House	0.150	--	Colouring Agent
36	Erythrosine Lake	In-House	0.004	--	Colouring Agent
Polishing					
37	Carnauba Wax	BP	0.130	--	Polishing Agent

Where, BP: British Pharmacopoeia, q.s.: quantity sufficient

3. Pharmaceutical Form: Enteric coated Tablet

4. Clinical Particulars:

4.1 Therapeutic Indications

MIMORAL is indicated for

- Swelling (edema), especially those caused by inflammation (e.g. swelling of the tooth or swelling of the gums). This medicine is highly effective in the treatment of swelling and can quickly reduce edema.
- Treatment of hematomas.
- After surgical trauma.
- Mimoral is used to treat necrotic tissue
- It is used to treat pelvic inflammatory diseases
- It is also used to treat chronic respiratory diseases. Mimoral drug reduces viscosity of mucus, thus facilitating its elimination
- This drug is used to treat different types of muscle and joint injuries, accompanied by swelling
- Mimoral can be taken after your cesarean section.
- Used to treat sciatica
- It can be taken after hysterectomy (uterus removal)
- To help loosen phlegm in asthma, bronchitis, lung diseases, and sinus infections.

4.2 Posology and method of administration

It needs to be taken on an empty stomach (usually 1-2 hours before taking food). It should be taken as soon as possible after symptoms of the swelling appear, because then this drug has shown best efficacy.

The dose depends on the severity of the condition. In severe conditions doctor may recommend you to take two pills of this medicine three times a day. After stabilization, the dose may be reduced to one pill of Mimoral four times a day.

It has to be used concomitant with appropriate antibiotics, to treat bacterial infections.

Mimoral tablets should always be used 1-2 hours before taking food, with a full glass of water. Swallow the tablets whole (do not crush them or chew them). You need to use this drug for as long as your doctor tells you to. It usually takes 10 days until the swelling completely disappears.

It also should be avoided in combination with alcoholic beverages because it increases the risk of side effects.

4.3 Contraindications

Hypersensitivity to Mimoral Tablet is a contraindication. In addition, Mimoral Tablet should not be used if you have the following conditions:

- Breastfeeding
- Fresh blood clots
- Hypersensitivity
- Pregnant

4.4 Special warnings and precautions for use

Glaucoma, as a complication of use of Chymotrypsin in cataract extractions pt, has occurred usually with 2-5 days after operation. There have been practically no indications of longer persisting glaucoma, from use of the enzyme.

Pregnancy and breast-feeding: Not enough is known about the use of Chymotrypsin during pregnancy and breast-feeding. Stay on the safe side and avoid use.

Mimoral should be avoided in patients allergic to trypsin or chymotrypsin or other similar enzymes. Symptoms of an allergy can include:

- skin rash,
- redness of the skin,
- itching of the skin,
- swelling of the throat, tongue and face,
- Trouble breathing.
- Allergic reaction can be life-threatening. Immediately contact your doctor if you are experiencing any of the allergy symptoms.

It may have some sugar, and therefore should be avoided in patients with disorders of carbohydrate metabolism.

Mimoral is not recommended for use during pregnancy and breastfeeding.

It should be avoided or may be used only with extra precautions in patients with liver disorders, kidney disorders or coagulation (**blood clotting**) disorders.

Also, it should not be used concomitant with alcoholic beverages.

4.5 Interaction with other medicinal products and other forms of interaction

Mimoral should be avoided or may be used only with extra precautions in combination with the following medications:

- Acids, bases, and antiseptics. These medicines may reduce the efficacy of trypsin and chymotrypsin (active compounds of Mimoral).
- Chloramphenicol, medicine used to treat infections (an antibiotic). Chloramphenicol reduces efficacy of Mimoral, therefore it should not be used concomitant with Mimoral.
- 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.

Tell your doctor about all medications and herbal medicines you are taking.

4.6 Pregnancy and LactationPregnancy

Mimoral is not recommended for pregnant women and nursing mothers. It should be used during pregnancy only if the benefit to the mother outweighs the risk to the child.

There is no data on whether if Mimoral passes into breast milk. It is recommended to avoid breastfeeding while using this drug. It will take at least 48 hours after the last time you have used Mimoral before you can start breastfeeding again.

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 Mimoral Tablet medicine 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. Please check for these effects on your body when using Mimoral Tablet. Always consult with your doctor for recommendations specific to your body and health conditions.

4.8 Undesirable effects

Mimoral may cause the following side effects: nausea, vomiting, abdominal pain, bloating, blood in the urine, allergy. Side effects occur very rarely.

It may cause an allergic reaction. Symptoms of an allergic reaction include: skin rash, itching, redness, swelling of the face, swelling of the tongue, swelling of the throat, difficulty breathing. Allergic reactions can lead to anaphylactic shock

4.9 Overdose

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

5. Pharmacological Particulars:

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Enzymes

ATC code:B06AA07, B06AA04

Mechanism of Action:

Trypsin and Chymotrypsin are two different but related digestive enzymes produced and released by the pancreas. Both enzymes function within the intestine to help break down large protein molecules that we ingest in the foods we eat. Without this enzyme-aided digestion, you would be unable to get the essential amino acids required for tissue building and repair. Because these two enzymes break down proteins, they classified as proteases.

5.2 Pharmacokinetic 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. These enzyme types of proteases are serine, threonine, cysteine, aspartic and metallo proteases. Trypsin and Chymotrypsin are two types of proteases in the serine family. Proteases are being used more and more medically and diagnostically in medicine for a multitude of health reasons including the treatment of pancreatic disease and cancer metastases. Trypsin and Chymotrypsin are 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.

5.3 Pre-clinical Safety:

Not applicable.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Lactose	BP
Maize Starch	BP
Microcrystalline Cellulose	BP
Povidone	BP
Purified Water	BP
Colloidal Anhydrous Silica	BP
Sodium starch Glycolate	BP
Purified Talc	BP

Magnesium Stearate	BP
Win coat (Clean Enteric Coat)	BP
Isopropyl Alcohol	BP
Dichloromethane	BP
Calcium Carbonate	BP
Acacia (Gum Acacia)	BP
Gelatin	BP
Methyl Paraben	BP
Propyl Paraben	BP
Sugar	BP
ColourPonceau 4R Lake	In-House
Erythrosine Lake	In-House
Carnauba Wax	BP

6.2 Incompatibilities:

None known.

6.3 Shelf Life:

36 months.

6.4 Special Precautions for storage:

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:

Alu-Alu strip of 10 tablets, Such 3 strips are packed in a Primary Carton along with the Pack insert.

6.6 Special precautions for disposal and other handling:

None

7. Marketing Authorization Holder:

MVC Pharmaceuticals

Shop No.1, Ground Floor,

Parasmani Apt., Daheli.Bhilad,

Tal-Umergam, Dist.-Valsad-396105

Gujarat

8. Marketing Authorization Number: --

9. Date of first Authorization /renewal of the authorization: --

10. Date of revision of text: September 2017