



Bharat Parenterals Limited

Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

BIOMORAL TABLETS - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product:

1.1 Generic Name/INN Name:

Trypsin – Chymotrypsin Tablets

Trade Name:

BIOMORAL TABLETS

1.2 Strength:

Trypsin - Chymotrypsin (6:1) eq. to 50000 USP

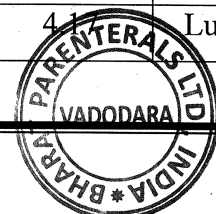
Units of Proteolytic enzyme activity

1.3 Pharmaceutical form:

Solid Oral Dosage form (Tablet)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients.	Spec.	Qty. / Tab mg.	Qty. / Tab mg	% w/w	Function
1.	Maize Starch	BP	30.108	30.108	15.68	Diluent
2.	Calcium Hydrogen Phosphate	BP	27.027	27.027	14.08	Diluent
3.	Maize Starch	BP	3.604	3.604	1.88	Binder
4.	Gelatin	BP	0.901	0.901	0.47	Binder
5.	Methyl Hydroxybenzoate	BP	0.180	0.180	0.09	Preservative
6.	Propyl Hydroxybenzoate	BP	0.090	0.090	0.05	Preservative
7.	Purified Water	BP	12.613	12.613	-----	Vehicle
8.	Lactose	BP	33.292	32.690	17.03	Diluent
9.	Maize Starch	BP	23.378	23.378	12.18	Diluent
10.	Microcrystalline cellulose (Avicel PII 112)	BP	12.189	12.189	6.35	Diluent
11.	Trypsin Chymotrypsin (6:1) equivalent to 50000 USP units of proteolytic enzyme activity	IH	18.030	19.833	10.33	Active
12.	Magnesium Stearate	BP	8.000	8.000	4.1	Lubricant





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13.	Sodium Starch Glycolate	BP	10.000	10.000	5.21	Disintegrant
14.	Colloidal Anhydrous Silica	BP	2.000	2.000	1.04	Disintegrant
15.	Purified Talc	BP	10.000	10.000	5.21	Diluent
16.	Isopropyl Alcohol	BP	105.000	105.00	-----	Coating Solvent
17.	Dichloromethane	BP	35.000	35.000	-----	Coating Solvent
18.	Colorcoat EC4S-B Red SE 6180411 A	IH	14.400	10.200	5.31	Coating Agent
19.	Colorcoat MB-20	IH	1.800	1.20	0.94	Coating Agent
			Total	192.00 mg	100.00 %	-----

3. Pharmaceutical form:

Dosage Form: Tablets (Oral solid dosage form)

Visual & Physical characteristics of the product: A red coloured, circular shape, biconvex, enteric coated tablets.

4. Clinical particulars:

4.1 Therapeutic indications:

Trypsin + Chymotrypsin, a combination of therapeutic enzymes, are prescribed for the treatment of active inflammatory edema associated with post-surgical wounds, traumatic injuries, pelvic inflammatory disorders and sciatica.

Trypsin + Chymotrypsin are also prescribed for rhinitis, sinusitis, as an additive for antibiotic therapy, to lower mucus viscosity (mucoviscidosis) and phlegm in bronchitis.

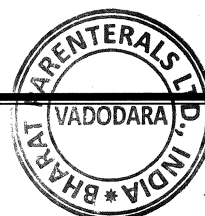
4.2. Posology and method of administration:

Since damage to the enteric coating rapidly causes loss of potency, the tablets should be swallowed whole without crushing or sucking. Regular intervals between intakes should be observed to ensure a permanent blood concentration.

Adults:

In medical indications: 2 tablets 4 times daily for about 4 days. Thereafter 1 tablet 4 times daily for another 4 days.

BIOMORAL TABLETS (Trypsin – Chymotrypsin Tablets)





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5.2 Pharmacokinetic properties:

It is observed in some studies that proteolytic enzymes are able to increase the permeability of the mucosal epithelium and, hence, facilitate their own absorption by a mechanism of self- enhanced para cellular diffusion.

5.3 Preclinical safety data

No data available

6. Pharmaceutical particulars:

6.1. List of Excipients:

Maize Starch
Calcium Hydrogen Phosphate
Gelatin
Methyl Hydroxy benzoate
Propyl Hydroxy benzoate
Purified Water
Lactose
Microcrystalline Cellulose
Magnesium Stearate
Sodium Starch glycolate
Colloidal Anhydrous Silica
Purified Talc

6.2 Incompatibilities:

None known

6.3. Shelf life:

36 months

6.4. Special precautions for storage:

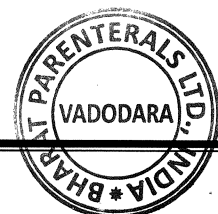
Store below 30°C. Protected from light

6.5. Nature and contents of container:

10 Tablets are packed in 1 Alu-Alu strip. Such a 5 Alu-Alu strips are packed in 1 printed carton with 1 leaflet.

6.6. Special precautions for disposal:

No special requirement.





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In surgery and dentistry: 2 tablets 4 times daily during the 2-3 days proceeding intervention. Thereafter 2 tablets 4 times daily for 3 to 8 days.

Children: 1 tablet per day and per 5 kg weight as soon as the child can swallow without sucking or chewing

4.3. Contraindications:

Hypersensitivity with any component of the tablet

4.4 Special warnings and precautions for use:

Trypsin + Chymotrypsin are contraindicated in patients with bleeding disorders, renal and/or hepatic disorders.

4.5 Interaction with other medicinal products and other forms of interaction:

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products especially of: other wound care products (e.g. antiseptics, antibiotics applied on the skin)

4.6 Pregnancy and lactation:

No information available

4.7. Effects on ability to drive and use machines:

No data available

4.8 Undesirable effects:

Trypsin + Chymotrypsin can cause shivering during recovery stages, hepatic damage including necrotic damage and cardiac arrhythmia.

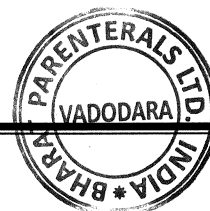
4.9. Overdose:

This medicine may be harmful if inhaled or swallowed in excess. If inhalation, swallowing or overdose is suspected, contact your local poison control center or emergency room immediately

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

After administration, Trypsin + Chymotrypsin are absorbed into the circulatory system. The therapeutic enzymes exert action of alpha-1 anti-trypsin and alpha-2 macroglobulin that results in degradation of such factors. These parameters are elevated after tissue damage and injury. Such mediators are responsible for fibrinolytic shutdown and maintenance of edema (inflammatory) that delay the healing process. Trypsin + Chymotrypsin improve the action of plasmin and clear the microcirculation, reduce edema and facilitate the healing process





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7. Applicant

Name and Address of Applicant

M/s. Biomedicine Sckivs Pharm.Nig Ltd,

Premise Address: No. 16, Anionwu Street Odoakpu, P.O.BOX:7846, Onitsha Nigeria,

Tel: +234803507884, +2348024517997.

E-mail: sckivspharm@yahoo.com

Name and Address of manufacturer:

M/s. BHARAT PARENTERALS LIMITED

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