SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RIBATRAN, coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TRYPSIN .....4.20 microkatals
PANCREATIC RIBONUCLEASE .....0.33 microkatals
CHYMOTRYPSINOGEN .....93.40 microkatals
For a coated tablet.

Excipients with known effects: lactose, sunset yellow FCF (E110), wheat starch (gluten)
For the complete list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adjunctive treatment of post-traumatic or postoperative edema.

4.2 Posology and method of administration

RESERVED FOR ADULTS

Oral route:
1 tablet, 3 times a day.
The tablet should be swallowed with a little water.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Warnings and special precautions for use

Not applicable

4.5 Interactions with other medicinal products and other forms of interaction

Not applicable

4.6 Pregnancy and breastfeeding

There are no reliable data on teratogenicity in animals.
In clinical practice, no specific malformations or fetotoxic effects have been observed to date. However, the follow-up of pregnancies exposed to this drug is insufficient to rule out all risks.
Therefore, as a precaution, it is best not to use this medication during pregnancy.

Due to the lack of data on the passage of this drug into breast milk, its use should be avoided during breastfeeding.

4.7 Effects on the ability to drive vehicles and use machinery

4.8 Undesirable effects

In some cases, an allergic sensitivity to this medication may exist or develop, which should lead to discontinuation of its use.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions is important. It allows for continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals must report any suspected adverse reactions according to the procedures defined in the Therapeutic Use and Data Collection Protocol (PUT RD).

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class : ENZYMOTHERAPY for anti-edema purposes, ATC code: M09AB52 (M. Musculoskeletal system)

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core: colloidal silica hydrate, wheat starch (gluten), microcrystalline cellulose, magnesium stearate, crospovidone, lactose.

Coating: titanium dioxide (E171), quinoline yellow (E104), sodium lauryl sulfate, methacrylic acid, sunset yellow FCF (E110), sodium bicarbonate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at a temperature below 30°C.

6.5 Nature and capacity of container

Thermoformed blister pack (aluminium/polyvinylidene chloride/ poly(vinyl chloride) of 20 coated tablets.

6.6 Operating instructions, handling instructions

No special requirements.

7. OPERATORS AND MANUFACTURERS

Operator of the export marketing authorization
FRILAB SA
17, rue des Pierres du Niton
1207 Geneva SWITZERLAND

Manufacturers:
Helios Pharmaceuticals
Malpur Village
Baddi, District. Solan
India

Alternative site:
Amoun Pharmaceuticals Cairo
Egypt

8. DATE OF REVISION OF THE TEXT

29 July 2022.

9. DOSIMETRY

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List II