

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF DRUG RIBATRAN, coated tablet

#### 2. Qualitative and quantitative composition

Trypsin .....	4.20 microkatalas
RIBONUCLEASE pancreatic .....	0.33 microkatalas
Chymotrypsinogen .....	93.40 microkatalas

For a coated tablet.

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Coated tablet.

### 4. CLINICAL DATA

#### 4.1 Therapeutic indications.

Adjuvant treatment of post-traumatic or post-operative edema.

#### 4.2 Dosage and method of administration

RESERVED FOR ADULTS

Oral:

1 tablet, 3 times daily.

The tablet should be swallowed with a little water.

#### 4.3 Contraindications

This medicine is against-indicated in cases of: hypersensitivity to any of the tablet components.

#### 4.4 Special warnings and precautions for use

#### 4.5 Interaction with other drugs and other forms of interaction

#### 4.6 Pregnancy and lactation

There are no reliable data teratogenicity in animals.

Clinically, no malformative or foetotoxic particular has appeared to date. However, monitoring of pregnancies exposed to this drug is insufficient to exclude any risk.

Consequently, as a precautionary measure, it is preferable not to use this medicine during pregnancy.

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

#### 4.7 Effects on ability to drive and use machines

#### 4.8 Undesirable effects

In some cases sensitization to the drug may exist or develop which should lead to stop its use.

#### **4.9 Overdose**

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Antioedematous enzymotherapie (locomotive system)

#### **5.2 pharmacokinetic properties**

#### **5.3 Preclinical safety data**

### **6. PHARMACEUTICAL DATA**

#### **6.1 List of excipients**

Anhydrous colloidal silica, pregelatinized starch, microcrystalline cellulose, Magnesium stearate, Crospovidine, lactose monohydrate, Acryl-EZE 93A0007 Orange, Triethyl Citrate, Dimethicone

#### **6.2 Incompatibilities**

#### **6.3 Shelf life**

3 years.

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

Store at a temperature below 30 ° C.

#### **6.5 Nature and content of container**

Blister (aluminum / polyvinylidene chloride / poly (vinyl chloride) 20 coated tablets.

#### **6.6 Operating instructions, instructions for handling**

No special requirements.

### **7. OPERATORS AND MANUFACTURERS**

#### **OWNER / OPERATOR TO INTERNATIONAL:**

FRILAB SA

17, rue des Pierres du Niton  
1207 Genève SWITZERLAND

**manufacturers:**

**1) Raw materials :**

BBI Enzymes SA (PTY) LTD  
19 Packer Avenue  
Epping 2 Eppindust  
South Africa-Cape Town 7475

**2) Finished Product**

Helios Pharmaceuticals  
Malpur Village  
Baddi, Disst. Solan  
india

Amoun Pharmaceuticals  
Cairo  
Egypt

**8. DOSIMETRY**

Not applicable.

**9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS**

Not applicable.

**CONDITIONS OF PRESCRIPTION AND DELIVERY**

Not applicable