SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MEGAMYLASE 200 U.CEIP/ml, syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Alfa-amylase.....200 U.CEIP*

For 1 ml.

*That is 142.86 European Pharmacopoeia units.

One teaspoon contains 2.8g of sucrose.

One tablespoon contains 8.4 g of sucrose.

Excipient with known effect: sucrose, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Adjunctive treatment of congestive conditions of the oropharynx (mild sore throat without fever).

Note: In the presence of general clinical signs of bacterial infection, systemic antibiotic therapy should be considered.

4.2. Posology and method of administration

Posology

Adult: 15 ml 3 times a day measured using a tablespoon or measuring cup.

Children over 3 years old (over 15 kg): 10 ml 3 times a day measured using 2 teaspoons or a measuring cup.

Infants and children from 6 months to 3 years (7 kg to 15 kg): 5 ml 3 times a day measured using a teaspoon or a measuring cup.

If there is no improvement after 5 days of treatment, it is necessary to seek medical advice.

Method of administration

Oral route.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Special warnings :

This medicine contains sucrose. Its use is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase-isomaltase deficiency.

This medicine contains 2.8 g of sucrose per teaspoon (5 ml) and 8.4 g of sucrose per tablespoon (15 ml), which should be taken into account in the daily intake in the case of a low-sugar diet or diabetes.

This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) and may cause allergic reactions (possibly delayed).

Precautions for use :

If other symptoms appear (severe sore throat, headache, nausea, vomiting…) or associated fever, the course of action

should be reassessed.

This medication should not be used for prolonged periods exceeding 5 days without medical advice.

4.5. Interactions with other medicinal products and other forms of interaction

No interaction studies have been conducted.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

There are no data on teratogenicity in animals.

In clinical practice, no 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.

Breastfeeding

In the absence of data on the passage of alpha-amylase into breast milk, the use of MEGAMYLASE should be avoided during breastfeeding.

4.7. Effects on the ability to drive vehicles and use machinery

No effects on the ability to drive vehicles and use machines were observed.

4.8. Undesirable effects

Undesirable effects are classified by organ system and frequency as follows: very common (>1/100, <1/10); uncommon (>1/1,000, <1/100); rare (>1/10,000, <1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders

Frequency not known: angioedema, urticaria, pruritus, rash, maculopapular rash.

Immune system disorders

Frequency not known: hypersensitivity, anaphylactic reaction, anaphylactic shock (see section 4.4).

Respiratory, thoracic and mediastinal disorders

Frequency not known: bronchospasm.

Gastrointestinal disorders

Frequency not known: nausea, vomiting

Statement of the effects unwanted suspected

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

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class : ANTI-INFLAMMATORY ENZYMES code ATC : R02A .

5.2. Pharmacokinetic properties

Not applicable

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of the excipients

Sucrose, glycerol, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), mandarin essential oil, citric acid monohydrate, purified water.

6.2. Incompatibilities

Without object.

6.3. Duration conservation

2 years

6.4. Special storage precautions

Store at a temperature not exceeding 25°C.

6.5. Nature and contents of container

125 ml of syrup in a bottle (type III brown glass) fitted with a cap (aluminium) and a seal (polyethylene) and a measuring cup.

6.6. Special precautions for disposal and handling

No particular requirements

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

7. OPERATORS AND MANUFACTURERS

Operator of the export marketing authorization

FRILAB LABORATORY
17. rue des Pierres du Niton
1207 Geneva
Swiss

Manufacturer

POLYMEDIC
Amyot d'Inville Street, Arsalane District
Casablanca
Morocco

8. DATE OF REVISION OF THE TEXT

July 28, 2022

9. DOSIMETRY

Without object.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

This medication is not subject to medical prescription.