SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

MEGAMYLASE 200 U.CEIP / ml syrup

2. Qualitative and quantitative composition

Alfa-amylase .... 200 U.CEIP *
To 1 ml.
* Either 142,86 European Pharmacopoeia units per ml of syrup.
One teaspoon contains 2.8 g sucrose.
One tablespoon contains 8.4 g sucrose.
known effect excipients: saccharose, sodium methyl parahydroxybenzoate (E219), sodium propyl paraben (E217).
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL DATA

4.1. Therapeutic indications

Adjuvant treatment of congestive states of the oropharynx.
NB: Before the general clinical signs of bacterial infection, systemic antibiotics should be considered.

4.2. Dosage and administration

Dosage

Adult : 15 ml 3 times per day measured using a spoon or a measuring cup.
Children over 3 years (over 15 kg) : 10 ml 3 times per day measured using 2 teaspoons or a dosing cup.
Infants and children 6 months to 3 years (7 kg to 15 kg) : 5 ml 3 times per day measured using a teaspoon or a measuring cup.
In the absence of improvement after 5 days of treatment, it is necessary to seek medical advice.

Administration mode

orally.

4.3. Cons-indications

Hypersensitivity to alpha-amylase or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions

Special warnings

This medicine contains sucrose. Its use is not recommended in patients with fructose intolerance, malabsorption of glucose and galactose or sucrase / isomaltase.
This medication contains 2.8 g sucrose per teaspoon (5 ml) and 8.4 g of sucrose per tablespoon (15 ml), to be taken into account in the daily ration in case of low-sugar diet or diabetes.
This drug contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) and may cause allergic reactions (possibly delayed).

Precautions

If other symptoms appear (major sore throat, headache, nausea, vomiting ...) or associated fever, what to do should be revalued.
This drug should not be used for prolonged periods, in excess of 5 days without medical advice.

4.5. Interactions with other drugs and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no teratogenicity data in animals.
Clinically, no teratogenic or foetotoxic effect 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.

feeding

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

4.7. Effects on ability to drive and use machines

MEGAMYLASE has no effect on ability to drive and use machines.

4.8. Side effects

Due to the presence of alpha-amylase, rare allergic reactions look may appear, usually skin, especially urticaria and / or angioedema.
Declaration of suspected adverse reactions
The reporting of suspected adverse reactions after drug approval is important. It allows continuous monitoring of the benefit / risk ratio of the drug. Health professionals report any suspected adverse reactions via the national reporting system: Agence française de sécurité sanitaire des produits de santé (ANSM) network of Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr.

4.9. Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Enzymes REFERRED TO ANTI-INFLAMMATORY, ATC code: R02A.

5.2. pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL DATA

6.1. List of excipients

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

6.2. incompatibility

Not applicable.

6.3. The duration of the conversation

24 months.

6.4. Special precautions for storage

Store at a temperature not exceeding 25 ° C.

6.5. Nature and contents of container

125 ml vial syrup (brown glass type III) with a stopper (aluminum) and a gasket (polyethylene) and a measuring cup.

6.6. Special precautions for disposal and handling

No special requirements.

7. OWNER AND OPERATOR MARKETING MARKETING AUTHORIZATION

La France :
LABORATORY LABORATORY TOP PHARM
FIELD MONTCAUSSON

BP 50
31250 REVEL
In export:
FRILAB LABORATORY
17 rue des Pierres du Niton
1207 Genève
Swiss

export manufacturer
POLYMEDIC Amyot d'Inville Street, District Arsalan - Casablanca-Morocco

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.