SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF DRUG

MEGAMYLASE 3000 U.CEIP, coated tablet

2. Qualitative and quantitative composition

Alfa-amylase .... 3000 U.CEIP *
For a coated tablet.
* Either 2142.9 European Pharmacopoeia units.
known effect Excipients: Sunset Yellow (E110), sucrose, sorbitol.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

coated tablets

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

For adults.
There is a syrup form most suitable for the child.

Dosage

1 tablet 3 times daily with meals.

Administration mode

Swallow the tablet without crushing it, with a glass of water.
In the absence of improvement after 5 days of treatment, it is necessary to seek medical advice.

4.3. Cons-indications

This medicine is against-indicated in the following situations:

- 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 drug contains sorbitol. Its use is not recommended in patients with fructose intolerance (rare hereditary disease).
This medication contains an azo coloring agent (E110, sunset yellow FCF) and may cause allergic reactions.

Precautions

If other symptoms appear (major sore throat, headache, nausea, vomiting ...) or associated fever, the conduct should be revalued.
This drug should not be used for prolonged periods beyond 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.

Breastfeeding

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

No effect on ability to drive and use machines have been observed.

4.8. Side effects

Due to the presence of alpha-amylase, rare allergic reactions 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

magnesium stearate, sorbitol, shellac, copolymer of butyl methacrylate, (2-dimethylaminoethyl) methacrylate and methyl methacrylate 1: 2: 1 (Eudragit E100), talc, gelatin, sucrose, gum arabic, titanium dioxide, yellow orange S (E110), carnauba wax.

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

24 coated tablets in blisters (PVC / PVDC / Aluminum).

6.6. Special precautions for disposal and handling

No special requirements.

7. OWNER AND OPERATOR MARKETING MARKETING AUTHORIZATION

La France :
LABORATOIRE TOP PHARM
DOMAINE DE MONTCAUSSON
BP 50
31250 REVEL
In export:
LABORATOIRE FRILAB
17 rue des Pierres du Niton
1207 Genève
Swiss

Subcontractors export
ROTTENDORF PHARMA, ZI N°2 Prouvy - Rouvignies, 1 rue Nungesser, 59121 Prouvy France

Alternative packaging site: POLYMEDIC, Rue Amyot d'Inville, Quartier 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.