

APPENDIX 1

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

HEXALYSE, tablet to be sucked

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BICLOTYMOL	5.0 mg
LYSOZYME HYDROCHLORIDE	5.0 mg
ENOXOLONE	5.0 mg
for one tablet to be sucked of 1200.0 mg	

Excipients: Icing sugar, orange yellow S (E110)
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet to be sucked.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Infectious inflammatory diseases of the oral mucosa (stomatitis, gingivitis including caused by dental prosthesis) pharynx, larynx caused hypersensitivity agents to biclotymol, lysozyme and enoxolole
Local treatment is over all indications of inflammatory and infectious diseases of the nasopharynx, acute and chronic pharyngitis, pharyngolaryngitis, tonsillitis, post tonsillectomy, glossitis

4.2 Posology and method of administration

Suck the tablets slowly, without chewing them.
Adults 1 tablets to be sucked every 2 hours
Eight tablets to be sucked during 24 hours, spreading out the doses.
Children under 6 years of age 1 tablets to be sucked every 4 hours
Four tablets to be sucked during 24 hours,
This medicine should not be used for an extended period exceeding 10 days.

4.3 Contra-indications

This medicinal product is contra-indicated in the following circumstances :

- Children under 6 years of age,
- Hypersensitivity to biclotymol or any other ingredients of the tablet.

The use should be avoided in patients with fructose intolerance, glucose-galactose malabsorption syndrome or a sucrase/isomaltase deficiency.

4.4 Special precautions for use

Special precautions for use:

If other symptoms should occur (significant sore throat, headaches, nausea, vomiting, etc.) or if there is a concomitant fever, the course of action should be re-assessed.

This medicine contains sucrose. The use should be avoided in patients with fructose intolerance, glucose-galactose malabsorption syndrome or a sucrase/isomaltase deficiency.

If the patient is diabetic or is on low sugar diet, take the quantity of icing sugar in each tablet into account in the daily allowance: 1.054 g.

This medicine contains a colouring agent (E110, Orange Yellow) and can induce allergic reactions.

4.5 Interactions with other medicaments and other forms of interaction

The simultaneous or successive use of local antiseptics has to be avoided, considering the possible interference (antagonism, inactivation).

4.6 Use during pregnancy and lactation

No reliable data are available to evaluate the teratogenicity in experimental animals.

Clinical experience has so far shown no malformations or foetotoxic effects.

As a result, this medicinal product should only be used by pregnant and breast-feeding women if strictly necessary

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed

4.8 Undesirable effects

Possibility of local allergic reaction, super infection.

During long-term use possible oral dysbacteriosis, proliferation risk of bacterial or fungal infections.

If any of these side effects notice in the instruction are compounded or if you notice any other side effects not mentioned in the instructions inform your doctor

This medicine contains a colouring agent (E110, Orange Yellow) and can induce allergic reactions

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

FOR ANTI-INFLAMMATORY AND ANTISEPTIC USE
(R : respiratory system)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lemon essential oil, citric acid monohydrate, orange yellow S (E110), magnesium stearate, gum arabic, icing sugar.

6.2 Incompatibilities

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Store at a temperature below 25°C.

Keep away from children

6.5 Nature and contents of container

Thermoformed blister pack (PVC/PVdC/Aluminium). 30 tablets in a pack (3x 10)

6.6 Instructions for use and handling

7. MARKETING AUTHORIZATION HOLDER

BOUCHARA-RECORDATI
70 Avenue du Général de Gaulle
92 800 PUTEAUX

8. MARKETING AUTHORIZATION NUMBER

313 252.9: 30 tablets to be sucked in thermoformed blister packs (PVC/PVdC/Aluminium)

360 941.1: 20 tablets to be sucked in thermoformed blister packs (PVC/PVdC/Aluminium)

363 849.9: 24 tablets to be sucked in thermoformed blister packs (PVC/PVdC/Aluminium)

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

May 1998.

10. UPDATE OF THE TEXT

May 2015

11. DOSIMETRY

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

CONDITIONS FOR PRESCRIPTION AND DISPENSING

Drug without prescription.