APPENDIX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

HEXASPRAY, aerosol

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Biclotymol	750 mg
Benzyl alcohol	500 mg
Sodium edetate	2.5 mg
Methylparaben	25 mg
Anise essential oil (reconstitued)	30 mg
Ammonium glycyrrhizinate	20 mg
Sodium saccharin	50 mg
Dispersible cellulose	300 mg
Soybean lecithin	900 mg
Glycerol	1000 mg
Ethanol 96%	1060 mg
Purified water	s.q.f 30.0 g
Nitrogen (propulsive gas)	s.q.

For a bottle of 30 g.

3. PHARMACEUTICAL FORM

Aerosol.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

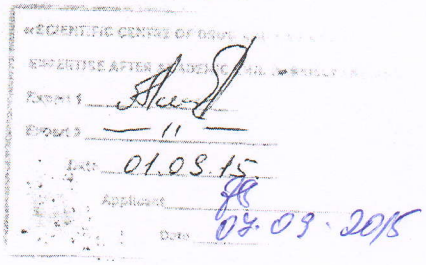
Local symptomatic treatment of acute oropharyngeal disorders.

4.2 Posology and mode of administration

FOR ADULT AND CHILD OVER 30 MONTHS ONLY.
Adults and children over 30 months : 2 sprays 3 times per day.
The treatment is limited to 5 days.

4.3 Contra-indications

- Hypersensitivity to active ingredient or to one of the excipients.
- Throat aerosol are contraindicated in infants below 30 months of age (risk of laryngospasm).
- Children under 6 years



4.4 Special warnings and special precautions for use

- The indication does not justify prolonged treatment for more than 5 days, in particular as this may disturb the homeostasis of the normal microbial flora of the oral cavity with a risk of spreading bacterial or fungal infection.

- Treatment should be reviewed if the symptoms persist for 5 days and/or if there is associated fever.

- The simultaneous or successive use of other antiseptics should be avoided because of possible interference (antagonism, inactivation).

4.5 Interaction with other medicaments and other forms of interaction

The simultaneous or successive use of other antiseptics should be avoided because of possible interference (antagonism, inactivation).

4.6 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 Information about negative influence on ability to drive and use machines

4.8 Adverse effects

Very rare:
Allergic disorders.
The presence of methyl parahydroxybenzoate (E218) and soybean lecithin may give rise to allergic reactions.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

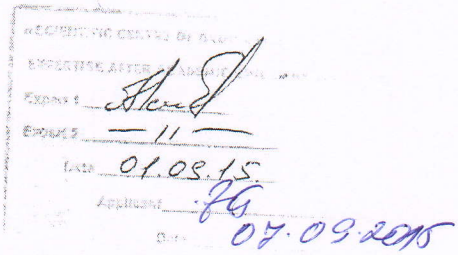
5.1 Pharmacodynamic properties

Pharmacotherapeutic class: Antiseptic for local applications.
ATC code : R02AA20 (R : Respiratory system)

Biclotymol is an antiseptic of biphenolic family.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data



6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Benzyl alcohol, sodium edetate, methylparaben, anise essential oil (reconstituted), ammonium glycyrrhizinate, sodium saccharin, dispersible cellulose, soybean lecithin, glycerol, ethanol 96%, purified water, nitrogen.

6.2 Shelf life

5 years.

6.3 Special precautions for storage

Keep away from children
Not above +25°C*

6.4 Nature and contents of containers

Bottle of 30 g . Glass container pressurized with nitrogen and stoppered with an inserted valve. The valve is fitted with a white press button. The top cap is in polyethylene.

6.5 Instructions for use and handling

Always shake the bottle before use.

7. MARKETING AUTHORIZATION HOLDER

BOUCHARA-RECORDATI
Immeuble " le Wilson "
70 avenue du General de Gaulle
92800 PUTEAUX, FRANCE

8. MARKETING AUTHORIZATION NUMBER

n°327 797.2 : Bottle of 30 g.

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

January 1985.

10. UPDATE OF THE TEXT

February 2013.

Date 01.08.15

Date 07.09.2015