

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

HEXASPRAY, aerosol

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Biclotymol.....750 mg

For a bottle of 30 g.

Excipient: methylparahydroxybenzoate (E218).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Aerosol.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Infectious - inflammatory treatment oropharyngeal disorders (including stomatitis, gingivitis), pharynx, larynx, caused by pathogens susceptible to biclotimol.

Topical treatment of inflammatory and infectious diseases of the nasopharynx and respiratory tract (acute and chronic pharyngitis, pharyngolaryngitis, tonsillitis, conditions after tonsillectomy, glossitis).

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 sprays are contraindicated in infants below 30 months of age (risk of laryngospasm).
- Due to the presence of soy lecithin, this medicine is contraindicated in case of allergy to peanuts or soya.

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).

-The presence of methyl parahydroxybenzoate (E218) and soybean lecithin may give rise to allergic reactions

4.5 Interaction with other medicaments and other forms of interaction

Non applicable.

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

Non applicable.

4.8 Adverse effects

Adverse reaction reported in the worldwide post marketing experience for which a reasonable casual relationship exists are listed under to the classification of MedDRA system organ class and frequency: very often ($> 1/10$), often (from $\geq 1/100$ to $< 1/10$), infrequently (from $\geq 1/1000$ to $< 1/100$), rarely (from $\geq 1 / 10\ 000$ to $< 1/1000$), very rare (from $< 1/10\ 000$), the frequency is unknown (the frequency cannot be calculated from the available data).

Immune system disorders: Very rare: lip oedema

Skin and subcutaneous tissues disorders: Very rare angioedema, erythema, rash, urticarial

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

Non applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class: Medicine with local action issued antibacterial. ATC code: R02AA20 (R: Respiratory system).

Biclotymol belongs to biphenolic family.

5.2 Pharmacokinetic properties

No data.

5.3 Preclinical safety data

No data

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

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

6.2 Incompatibilities

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store at a temperature below 25°C.

Keep away from children

6.5 Nature and contents of containers

8, 10, 15, 20 or 30 g container (glass), pressurized (with nitrogen) top cap (polyethylene).

6.5 Instructions for use and handling

Always shake the bottle before use.

7. MARKETING AUTHORIZATION HOLDER

BOUCHARA-RECORDATI
70 avenue du Général de Gaulle
92800 PUTEAUX, FRANCE

8. MARKETING AUTHORIZATION NUMBER

n°34009 333 923 6 9 : 8 g container (glass), pressurized (with nitrogen) top cap (polyethylene).
n°34009 333 898 1 9 : 10 g container (glass), pressurized (with nitrogen) top cap (polyethylene).
n°34009 333 899 8 7 : 15 g container (glass), pressurized (with nitrogen) top cap (polyethylene).
n°34009 333 900 6 8 : 20 g container (glass), pressurized (with nitrogen) top cap (polyethylene).
n°34009 327 797 2 7 : 30 g container (glass), pressurized (with nitrogen) top cap (polyethylene).

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

January 1985.

10. UPDATE OF THE TEXT

January 2017.

11. DOSIMETRY

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS CONDITIONS FOR PRESCRIPTION AND DISPENSING

Medicine not under prescription.