SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HEXASPRAY, Oromucosal spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Biclotymol……750 mg per 30 g.
Excipients with known effect: methyl parahydroxybenzoate (E218), benzyl alcohol
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oromucosal spray.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Local symptomatic treatment of acute oropharyngeal disorders.

4.2. Posology and method of administration

FOR ADULT AND CHILD OVER 30 MONTHS ONLY.

Posology

Adulte and child over 30 months: 2 sprays 3 times daily.
The treatment is limited to 5 days.

Method of administration

Oral use. Oropharyngeal use.
Always shake the spray before use. Hold vertically while spraying.

4.3. Contraindications

- Hypersensitivity to the active substance biclotymol, or any of the excipients listed in section 6.1.
- Children younger than 30 months of age (risk or laryngospasm).

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 imbalance 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 beyond 5 days and/or if there is associated fever.
- The simultaneous or successive use antiseptics with biclotymol should be avoided because of possible interference (antagonism, inactivation).
- This medicine contains methyl parahydroxybenzoate (E218) and may cause allergic reactions (possibly delayed);
- This medicine contains 35 mg benzyl alcohol in each dose (2 sprays). Benzyl alcohol may cause allergic reactions and mild local irritation.
- This medicine contains less than 1 mmol sodium (23 mg) per spray, that is to say essentially ‘sodium-free’.

4.5. Interaction with other medicinal products and other forms of interaction

Available data do not suggest the existence of clinically significant interactions.

4.6. Fertility, Pregnancy and lactation

Pregnancy

There are no or limited data from the use of biclotymol in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity.

HEXASPRAY, oromucosal spray is not recommended during pregnanacy and in women of childbearing potential not using contraception.

Breast feeding

There is insufficient data on the excretion of biclotymol or metabolites in human milk.
HEXASPRAY, oromucosal spray should not be used during breast-feeding.

Fertility

No fertility studies have been conducted in human.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Adverse reactions reported in the worldwide post-marketing experience for which a reasonable causal relationship exists are listed below by MedDRA system organ class and frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from available data).

Immune system disorders:

Very rare: Lip oedema.

Skin and subcutaneous tissus 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

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: based local action medicine with antibacterial purpose.

ATC code: R02AA19

Biclotymol belongs to biphenolic family. Biclotymol has an antibacterial based action on gram-positive cocci in following conditions: 15 minutes contact time at maximum concentration (90%).

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 30 °C. Keep away from heat.

6.5. Nature and contents of container

30 g container (glass), pressurized (with nitrogen) top cap (polyethylene).

6.6. Special Precautions for disposal

Shake before each use

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.1 MARKETING AUTHORISATION HOLDER

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106 16TH ROAD

MIDRAND

GAUTENG

SOUTH AFRICA

7.2 MANUFACTURED BY

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70 AVENUE DU GENERAL DE GAULLE

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FRANCE

7. MARKETING AUTHORISATION NUMBER

TAN 22 HM 0264

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th July, 2022

9. DATE OF (PARTIAL) REVISION OF TEXT