SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ACTISOUFRE, solution for nasal/oral spray in a pressurised container

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium monosulphide
quantity equivalent to sodium sulphide..... 13.00 mg
Saccharomyces cerevisiae type D* ..... 500.00 mg

per 100-ml container

* Yeast extract

Excipients: sodium (in the form of sodium chloride (900 mg) and saccharin sodium (35 mg)), sodium methyl parahydroxybenzoate (E219) (100 mg).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM: Solution for nasal/oral spray in a pressurised container.

4. CLINICAL DATA

4.1. Therapeutic indications

Used for chronic inflammatory conditions of the upper airways such as chronic rhinitis and rhinopharyngitis.

4.2. Posology and method of administration

By the nasal route

Adults and children

1 prolonged spray* into each nostril 3 times daily with the head tipped back.

Infants

1 spray into each nostril twice daily.

Administer the medicine with the infant lying on his/her side or sitting when old enough to sit up, with the infant's head tipped to the side in order to prevent laryngeal spasm.

Introduce the nasal nozzle into the nostril (short nozzle) into the nostril and spray strongly. Repeat the operation for the other nostril with the head tipped to the other side.

Do not:
Never spray into the nostrils when the infant's head is tipped backwards in order to prevent the liquid going into the throat.

* The spray time is 2 to 3 seconds for each nostril.

By the oral route

1 spray 3 times daily, directly into the oral cavity, then swallow.

* The spraying time is 2 to 3 seconds.

Introduce the oral nozzle (long, right-angled nozzle) into the oral cavity and press to deliver a dose of product.

Each pressurised container contains 100 ml, i.e. 90 sprays (of 2 to 3 seconds each).

During spraying, be careful to keep the top of the bottle upwards in order to prevent excessive consumption of propellant gas.

4.3. Contra-indications

Hypersensitivity to one of the ingredients of the product and, in particular, sulphur.

4.4. Special warnings and precautions for use

For the oral route and in the event of a low-salt diet, take into account the sodium intake, which is 4.2 mg of sodium per spray (i.e. 0.18 mmol of sodium/spray).

100 ml of solution (i.e. 90 sprays of 2 to 3 seconds each) contain 378 mg of sodium (i.e. 16.4 mmol of sodium/100 ml).

The presence of sodium methyl parahydroxybenzoate is liable to induce an allergic reaction of the delayed hypersensitivity type in subjects sensitive to preservatives of the parahydroxybenzoate series (and their derivatives).

4.5. Interactions with other medicinal products and other forms of interaction: Not applicable.

4.6. Pregnancy and lactation

In the absence of data on pregnancy and lactation, use of this medicine during pregnancy or lactation is not advised.

4.7. Effects on ability to drive and use machines:

Not applicable.

4.8. Adverse effects:

By the oral route: potential gastrointestinal disorders such as stomach ache.

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 Agence nationale de sécurité du medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.ansm.sante.fr

4.9. Overdose:

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: OTHER COLD PREPARATIONS; ATC code: R05X

(R: respiratory system)

Intake of sulphur in the form of sodium sulphide and trace elements and vitamins in the form of Saccharomyces cerevisiae yeast extract.

5.2. Pharmacokinetic properties:

Not applicable

5.3. Preclinical safety data:

Not applicable

6. PHARMACEUTICAL DATA

6.1. List of excipients

Saccharin sodium
Polysorbate 80
Sodium methyl parahydroxybenzoate (E219)
Sodium chloride
20% (m/v) chlorhexidine digluconate
Neroli compound essential oil A*
Purified water
Propellant gas: nitrogen.

*Composition of Neroli compound essential oil A: essential oils of bitter and sweet orange, geraniol, terpineol, linalol, methyl anthranylate, phenylethyl alcohol, geranyl acetate.

6.2. Incompatibilities:

Not applicable.

6.3. Shelf-life:

2 years.

6.4. Special precautions for storage:

Store at a temperature not exceeding 30 °C.

Pressurised container:
The container contains pressurised liquid. Do not expose to a temperature greater than 50°C. Do not pierce the container.

6.5. Nature and contents of container

100 ml of solution in a 150-ml (aluminium) pressurised container fitted with a nasal nozzle (PE/POM) and an oral nozzle (PE/PP/POM).

6.6. Special precautions for disposal and other handling

Fit the nasal nozzle (short nozzle) or oral nozzle (long, right-angled nozzle) depending on the administration route to be used.

Introduce the nasal nozzle into the nostril or the oral nozzle into the oral cavity and press to deliver a dose of product.

For each spray, be careful to hold the bottle top upwards or downwards in order to prevent excessive use of the propellant gas.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRES GRIMBERG: 19, rue Poliveau - 75005 Paris - France

8. MARKETING AUTHORISATION NUMBER(S)

- 351 671-5 or 34009 351 671 5 6: 100 ml of solution in a 150-ml pressurised container (aluminium) fitted with a nasal nozzle (PE/POM) and an oral nozzle (PE/PP/POM); box of 1.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

25th May 1994 /.10th December 2010

10. DATE OF REVISION OF THE TEXT:

12 April 2010

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription.