SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

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

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 with known effect:

Sodium (as sodium chloride and saccharin)

Sodium methyl parahydroxybenzoate (E219)

For a full list of excipients, see the section "List of excipients".

PHARMACEUTICAL FORM

Solution for nasal/oral spray in a pressurised container.

CLINICAL PARTICULARS

Therapeutic indications

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

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.

Pediatric population
Infants
1 spray into each nostril twice daily.

Administer the medicine in 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.

To be not done:
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 assessed at 2 to 3 seconds for each nostril.

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

*The spray time is assessed at 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.

Contra-indications

Hypersensitivity to the active substances and, in particular, sulphur or to any of the excipients listed in section ”List of excipients”.

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).

Fertility, pregnancy and Breast-feeding

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

Undesirable effects

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

Reporting of suspected undesirable effect
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: Agence nationale de sécurité du medicament et des produits de santé (ANSM) and network of the Regional Centres of Pharmacovigilance – Website: www;signalement-sante.gouv.fr

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class: OTHER COLD PREPARATIONS; ATC code: R05X

(R: respiratory system)

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

PHARMACEUTICAL PARTICULARS

List of excipients

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

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

Shelf-life

2 years.

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.

Nature and contents of external 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).

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.

MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

MARKETING AUTHORISATION NUMBER(S)

- 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.

DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

25 May 1994/25 May 2009

DATE OF REVISION OF THE TEXT

10 August 2017

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription.