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
Yeast extract *Saccharomyces cerevisiae* type D……500.00 mg
per 100-ml container

Excipients with known effect:

Sodium methyl parahydroxybenzoate (E219)

For the 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

Posology

Adults and children

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

Infants

One spray into each nostril twice daily.

Method of administration

Adults and children

*The time for a prolonged spray is estimated at 2 or 3 seconds for each nostril.

Infants

Administer the medicine into 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.

By the oral route

Posology

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

The prolonged spray time is assessed at 2 to 3 seconds.

Method of administration

Do not use the oral nozzle before 3 years old.
Before 3 years old, use the nasal nozzle regardless of the route of administration.

From 3 years old, insert the oral nozzle (long nozzle at a right angle) into the oral cavity then exert pressure to deliver a dose of product.

Each bottle contains 100 ml or 90 prolonged sprays.

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

This medicine contains less of 1 mmol sodium (23 mg) by oral spray, that is to say essentially "sodium free".

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 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: 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 group: OTHER COLD PREPARATIONS; ATC code: R05X

Mechanism of action

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 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

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

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

13 October 2020

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription.