SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

ACTISOUFRE 4 mg /50 mg per 10 ml, oral suspension or suspension for nasal instillation

QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium sulphide nonahydrate.....4.0 mg
Yeast of *Saccharomyces cerevisiae* .....50.0 mg

per 10-ml ampoule.

For a full list of excipients, see section “List of excipients”.

PHARMACEUTICAL FORM

Oral suspension or suspension for nasal instillation.

CLINICAL DATA

Therapeutic indications

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

Posology and method of administration

For special handling precautions see “Special precautions for disposal and other handling”.

By the nasal route:

Posology:

Two nasal irrigations per day.

Method of administration

- Shake the ampoule before opening it.
- Remove the cap and tip from dropper bottle
- Fill in the bottle with the contents of ampoule
- Stand in front of a wash-basin, tip slightly the head back and choose one of two following methods of administration:
  - Run ACTISOUFRE into a nostril by pressing the dropper bottle
    Breathe through the mouth while repeatedly saying the syllable 'kay'.
    Keep the head slightly back for a few moments (about 30 seconds) in order to let the product remain in contact with the secretions, then raise the head and swallow the secretions.

Or

  - If you want to swallow the minimum of secretions, you can proceed in the following manner:
- Block one nostril, sink ACTISOUFRE into the other nostril by pressing the drip bottle and perform 3 to 4 respiratory movements of backwards and forwards through the nostril containing the liquid, then straighten the head and exhale to expel the contents of the same nostril.
- Restart the same operation for the other nostril
- Repeat until the contents of the dropper bottle have been fully used
- After each use, minutely rinse the bottle under running water and dry it carefully.

By the oral route:

Posology:

- Children aged less than 5 years: 1 ampoule daily.
- Adults and children aged more than 5 years: 1 ampoule twice daily.

Method of administration

- **Children aged less than 5 years:**

Dilute the contents of an ampoule in a glass containing 10 ml of water, the volume of a dessert spoon, to be taken during a meal once a day.

- **Adults and children aged more than 5 years:**

Dilute the contents of an ampoule in a glass containing 10 ml of water, the volume of a dessert spoon, to be taken during a meal twice a day.

Contra-indications

Hypersensitivity to the active substances, and especially to sulphur or to any of the excipients listed in section "List of excipients**".**

Special warnings and precautions for use

By oral route:

This medicine contains 37 mg of sodium per ampoule, equivalent to 1.85% of the maximum daily dietary intake of 2 g of sodium per adult recommended by the WHO..

Fertility, pregnancy and lactation

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

Effects on ability to drive and use machines

The effects of ACTISOUFRE on the ability to operate vehicles and machines have not been studied.

Undesirable effects
By 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.signalement-sante.gouv.fr

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class: OTHER COLD COMBINATION PREPARATIONS - ATC code: R05X

Mechanism of action
Supply in sulfur by sodium sulphide and in trace elements and vitamins by yeast *Saccharomyces cerevisiae*.

PHARMACEUTICAL PARTICULARS

List of excipients

Saccharin sodium, polysorbate 80, Neroli flavor (essential oils of bitter orange and sweet orange, geraniol, terpineol, linalol, methyl anthranylate, phenylethyl alcohol, geranyl acetate), sodium chloride, purified water.

Shelf-life

3 years.

Special precautions for storage

Store in the original outer packaging.

Nature and contents of container

10 ml of suspension in an ampoule (brown glass) with dropper bottle.

Special precautions for disposal and other handling

- Shake the ampoule before opening it.
- Any remaining deposit is not active. The deposit consists of the walls of the yeast cells which have already released their soluble components (yeast extract containing vitamins, trace elements, etc.) into the ampoule beforehand. The residual deposit therefore does not impair the activity of the product.

The following procedure must be followed to empty a self-breakable ampoule in a container (the dropper bottle or a glass): take a peak between the thumb and the index finger and, in a dry motion, cause a rupture.
Introduce the open ampoule above the container and break the other tip in the same way.

- When the ampoule is open, the smell reflects the mixture of sulphur and orange blossom.

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

MARKETING AUTHORISATION HOLDER:

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

MARKETING AUTHORISATION NUMBER

- 34009 328 164 3 9 : 10-ml ampoule (brown glass); box of 30

DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

29 January 1992/29 January 2012

DATE OF REVISION OF THE TEXT

07 September 2020

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription.