SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

per 10-ml ampoule.

* Yeast
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension or suspension for nasal instillation.

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

Also see section 6.6

By the nasal route:

- Stand in front of a wash-basin, tip the head back, and run ACTISOUFRE into a nostril by strongly pressing the dropper bottle. Breathe through the mouth while repeatedly saying the syllable 'kay'.
- Allow the product to remain in contact with the secretions for a few moments (about half a minute).
- Repeat the procedure until the dropper bottle is completely empty.
- Repeat the same operation on the other nostril.
- Carefully rinse the bottle under running water and dry it carefully.

2 nasal irrigations daily.

By the oral route:

- Children aged less than 5 years: half an ampoule to 1 ampoule daily.
- Adults and children aged more than 5 years: 2 ampoules daily.

4.3. Contra-indications: Intolerance to sulphur.

4.4. Special warnings and precautions for use: Oral route: in the event of a low-sodium diet, take into account the sodium intake, which is about 1.6 mmol, i.e. 37 mg per ampoule.

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 the medicine during pregnancy or lactation is not advised.

4.7. Effects on ability to drive and use machines: Not applicable.

4.8. Adverse effects:
Potential gastrointestinal disorders such as stomach ache following oral administration.

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 COMBINATION PREPARATIONS

(R: respiratory system)

ATC code: R05X

Sulphur and yeast intake.

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

6.2. Incompatibilities: Not applicable.

6.3. Shelf-life: 3 years.

6.4. Special precautions for storage: Store in the original outer packaging.

6.5. Nature and contents of container: 10 ml of suspension in an ampoule (brown glass) with dropper bottle.

6.6. Instructions for use, handling and disposal

- 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.
- When the ampoule is opened, the odour reflects a mixture of sulphur and essential oil of orange flower.

BEWARE: ACTISOUFRE ampoules are self-breakable ampoules. To open the ampoule, take a tip between the thumb and the forefinger and break it open with a fast movement. Hold the open ampoule over the dropper bottle or a glass and break off the second tip.

By the nasal route:

- Remove the nozzle from the dropper bottle.
- Fill the bottle with the contents of an ampoule.

Also see section 4.2

By the oral route:

Dilute the contents of an ampoule in a little water and drink during a meal.

7. MARKETING AUTHORISATION HOLDER: LABORATOIRES GRIMBERG - 19, rue Poliveau - 75005 PARIS - France

8. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

3400936468146 or 364 681-4: 10-ml ampoule (brown glass); box of 18 – Not marketed
3400932470143 or 324 701-4: 10-ml ampoule (brown glass); box of 24 - Not marketed
3400932816439 or 328 164-3: 10-ml ampoule (brown glass); box of 30 - Marketed
3400935615039 or 356 150-3: 10-ml ampoule (brown glass); box of 60 - Not marketed

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

29th January 1992 / 29th January 2012

10. DATE OF REVISION OF THE TEXT

14th March 2014

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription.