

Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

Keep out of the reach of children

In this leaflet:

1. WHAT ACTISOUFRE, solution for nasal/oral spray in a pressurised container IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU USE ACTISOUFRE, solution for nasal/oral spray in a pressurised container
3. HOW TO USE ACTISOUFRE, solution for nasal/oral spray in a pressurised container
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE ACTISOUFRE, solution for nasal/oral spray in a pressurised container
6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT ACTISOUFRE, solution for nasal/oral spray in a pressurised container IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class: Other cold medications, ATC code: R05X (R: respiratory system)

This medicine is recommended for chronic inflammatory conditions of the upper airways such as chronic rhinitis and rhinopharyngitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ACTISOUFRE, solution for nasal/oral spray in a pressurised container

Never use ACTISOUFRE, solution for nasal/oral spray in a pressurised container:

- if you are allergic (hypersensitive) to the active substances and, in particular, the sulphur or to any of the other ingredients of this medicine listed in section 6.

Warnings and precautions:

Take care with ACTISOUFRE, solution for nasal/oral spray in a pressurised container in the following cases:

For the oral route and in the case of a low-salt (salt-free) 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 contains 378 mg of sodium (i.e. 16.4 mmol of sodium/100 ml).

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

Other medicines and ACTISOUFRE, solution for nasal/oral spray in a pressurised container:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast feeding and fertility

Use of this medicine during pregnancy or breast feeding is not advised.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

ACTISOUFRE, solution for nasal/oral spray in a pressurised container contains sodium (in the form of chloride (900 mg) and saccharin (35 mg), and sodium methyl parahydroxybenzoate (E219) (100 mg).

3. HOW TO USE ACTISOUFRE, solution for nasal/oral spray in a pressurised container

Posology

By nasal route

Adults and children

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

Use in infants

1 spray into each nostril twice daily.

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

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 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.

By oral route

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

Intake of sodium: 4.2 mg of sodium per spray (i.e. 0.18 mmol of sodium/spray).

As a hygienic measure, clean the nasal or oral nozzle after each use.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

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

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.

Nasal nozzle diagram



Oral nozzle diagram



Pictogram showing that the bottle is not to be held horizontally.

If you use more ACTISOUFRE, solution for nasal/oral spray in a pressurised container, than you should:
Immediately consult your doctor or pharmacist.

If you forget to use ACTISOUFRE, solution for nasal/oral spray in a pressurised container:
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Potential stomach ache with the solution administered by oral route.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Web site: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ACTISOUFRE, SOLUTION FOR NASAL/ORAL SPRAY IN A PRESSURISED CONTAINER

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the cardboard box after EXP. The expiry date refers to the last day of that month

Store at a temperature not exceeding 30°C.

Pressurised container:

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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

- The active substances are:

Sodium sulphide

quantity equivalent to sodium sulphide13.00 mg

Saccharomyces cerevisiae type D*500.00 mg

per 100-ml bottle.

* Yeast extract

- The other ingredients are:

Saccharin sodium, polysorbate 80, sodium methyl parahydroxybenzoate (E219), 20% chlorhexidine digluconate solution, sodium chloride, Nérolí flavour*, purified water

*Composition of the Nérolí flavour: essential oils of citrus aurantium and sweet orange, geraniol, terpineol, linalol, methyl anthranilate, phenylethyl alcohol, geranyl acetate.

What ACTISOUFRE, solution for nasal/oral spray in a pressurised container looks like and contents of the pack

This medicine is a solution for nasal/oral spray in a 100-ml pressurised container with 2 nozzles: a nasal nozzle and an oral nozzle.

Marketing Authorisation Holder:

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

Manufacturer:

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This leaflet was last revised in August 2017

Detailed information on this medicinal product is available on ANSM website (France)