

# PACKAGE LEAFLET

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

**Read all of this leaflet carefully before you start taking this medicine. It contains important information on your treatment.**

If you have any further questions, if in doubt, ask your doctor or pharmacist.

- Keep this leaflet, you may need to read it again.
- If you need further information and advice, ask your pharmacist.
- If the symptoms get worse or persist, consult a doctor.
- If you notice any side effects not listed in this leaflet or if any of the side effects get serious, please tell your doctor or pharmacist.

### **In this leaflet:**

1. WHAT IS ACTISOUFRE, solution for nasal/oral spray in a pressurised container AND WHEN IS IT USED FOR?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING 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. WHAT ARE THE POSSIBLE SIDE EFFECTS ?
5. HOW TO STORE ACTISOUFRE, solution for nasal/oral spray in a pressurised container ?
6. FURTHER INFORMATION

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

Pharmacotherapeutic class: OTHER COLD PREPARATIONS.

(R: respiratory system).

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

### **2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING 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 ingredients of the product and, in particular, the sulphur contained in ACTISOUFRE, solution for nasal/oral spray in a pressurised container.

#### **Take special 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).

#### **Taking or using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### **Pregnancy and breast feeding**

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

Ask your doctor or pharmacist for advice before taking any medicine.

**List of excipients with known effect:**

Sodium (in the form of sodium chloride and saccharin sodium),

Sodium methyl parahydroxybenzoate (E219).

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

**Dosage**

**By nasal route**

**Adults and children**

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

**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 USE ACTISOUFRE, solution for nasal/oral spray in a pressurised container, EXACTLY AS YOUR DOCTOR HAS TOLD YOU.

**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:**  
Inform 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 the forgotten dose.  
If you have further questions on the use of this product, ask your doctor or pharmacist.

#### **4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?**

Like all medicines, ACTISOUFRE, solution for nasal/oral spray in a pressurised container, can cause side effects, although not everybody gets them.

Potential stomach ache with the solution administered by oral route.

#### **Statement of the side effects:**

If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and health products (Ansm) and the Regional Centers of Pharmacovigilance. The web site: [www.anism.sante.fr](http://www.anism.sante.fr) By reporting the adverse events, you contribute to supply more information on the medicine safety.

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

Keep out of the reach and sight of children.

Do not use ACTISOUFRE, solution for nasal/oral spray in a pressurised container, after the expiry date which is stated on the box and container. The expiry date refers to the last day of the 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.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. FURTHER INFORMATION**

**What does ACTISOUFRE, solution for nasal/oral spray in a pressurised container, contain ?**

#### **The active substances are:**

Sodium sulphide  
quantity equivalent to sodium sulphide .....13.00 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, Neroli compound essential oil A (essential oils of bitter orange and sweet orange, geraniol, terpineol, linalol, methyl anthranilate, phenylethyl alcohol, geranyl acetate), purified water.

**What is ACTISOUFRE, solution for nasal/oral spray in a pressurised container and contents of the outer 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 - 19, rue Poliveau - 75005 Paris- France

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