

## Package leaflet: Information for the patient

### 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.

#### **What is 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 group: Other cold medications, ATC code: R05X (R: respiratory system)**

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

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

**Do not use ACTISOUFRE, solution for nasal/oral spray in a pressurised container:**

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

#### **Warnings and precautions:**

Talk to your doctor or pharmacist before using ACTISOUFRE, solution for nasal/oral spray in a pressurised container:

#### **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, 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 methyl parahydroxybenzoate (E219) and sodium.**

The presence of sodium methyl parahydroxybenzoate may cause allergic reaction type of delayed hypersensitivity reactions in subjects sensitive to preservatives from the parahydroxybenzoate family (and their derivatives). This medicine contains less than 1 mmol sodium (23 mg) per oral spray, that is to say essentially "sodium free".

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

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

### **By nasal route**

#### **Adults and children**

The recommended dose is one prolonged spraying\* into each nostril 3 times daily with the head tipped back.

#### **Use in infants**

One spraying into each nostril twice daily.

### **Method of administration**

#### **Adults and children**

Put on the nasal tip (short nozzle) (see diagram). Introduce the nasal nozzle into nostril then exert pressure to deliver a dose of the product.

\* The prolonged spraying time is 2 to 3 seconds for each nostril.

For each spraying, be careful to hold the bottle top upwards or downwards in order to prevent excessive use of the propellant gas.

#### **Use in infants**

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 laryngospasm.

Introduce the nozzle into the nostril and make a straight spraying strongly.

Repeat the operation for the other nostril with the head tipped to the other side.

#### **What not to do:**

Never make a spraying into the nostril when the infant's head is tipped backwards in order to prevent the liquid going into the throat.

### **By oral route**

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

The prolonged spraying time is 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 administration route.

From 3 years old:

Fit the oral nozzle (long, right-angled nozzle) (see diagram).

Introduce the oral nozzle into the oral cavity and press to deliver a dose of product.

For each spraying, 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**



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

Do not use the bottle 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 the dose you forgot.

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 by oral route.

#### **Reporting of side effects:**

If you get any side effect, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system.

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.

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 use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month

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 monosulphide

quantity equivalent to sodium sulphide ..... 13.00 mg

Yeast extract *Saccharomyces cerevisiae* type D ..... 500.00 mg

Per 100-ml bottle.

- The other ingredients are:

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

\*Composition of the Neroli 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. Box of 1 bottle.

##### **Marketing Authorisation Holder:**

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

**Manufacturer:**

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