

Package leaflet: Information for the user

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

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 4mg / 50 mg, oral suspension or suspension for nasal instillation IS AND WHAT IT IS USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACTISOUFRE 4mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?
3. HOW TO TAKE ACTISOUFRE 4mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?
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1. WHAT ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: Other cold medications, ATC code: R05X

This medicine supplies sulphur and yeast in the form of sodium sulphide nonahydrate and *Saccharomyces cerevisiae*.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?

Do not take ACTISOUFRE 4 mg / 50 mg per 10 mL, oral suspension or suspension for nasal instillation in the following case:

- if you are allergic 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 taking ACTISOUFRE 4 mg / 50 mg per 10 mL, oral suspension or suspension for nasal instillation.

Other medicines and ACTISOUFRE 4 mg / 50 mg per 10 mL, oral suspension or suspension for nasal instillation

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

Pregnancy and breast feeding

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 4 mg / 50 mg per 10 mL, oral suspension or suspension for nasal instillation contains sodium.

This medicine contains 37 mg sodium (main component of cooking/table salt) per ampoule. This is equivalent to 1.85% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation

Always take this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you feel that Actisoufre 4 mg/50 mg per 10 ml, oral suspension or suspension for nasal instillation is too strong or too weak: consult your physician or your pharmacist.

- Shake the ampoule before opening it.
- Any possible remaining deposit is not active. The deposit consists of the walls of the yeast cells which 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.
- In order to empty a self-breakable ampoule into the container (a dropper bottle or a glass), you should act like follows: 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 the second tip off in the same way.
- When the ampoule is opened, the odour testifies to a mixture of sulphur and essential oil of oranger flower.

By nasal route:

Posology:

2 nasal irrigations daily.

Method of administration:



- Remove the nozzle from the dropper bottle.
- Fill the bottle with the contents of an ampoule.
- Stand in front of a wash-basin, lean your head back and choose one of the following methods of administration:
 - Let ACTISOUFRE run into a nostril by pressing the dropper bottle. Breathe through the mouth while keeping saying the syllable “kay”. Keep your head slightly leaned during a few moments (about 30 seconds) in order to get the product in contact with the secretions, then right your head and swallow the secretions

Or

- If you want to swallow as less as possible of secretions you can block one nostril and let Actisoufre run in another nostril while pressing on the dropper bottle and perform 3 to 4 breathing movements up and down in the nostril filled with the solution, then raise your head and expel the solution by expiration of the same nostril
- Repeat the same procedure for another nostril
- Repeat the same procedure in each nostril until the content of the dropper bottle is completely empty
- After each administration, rinse carefully the dropper bottle and the nozzle with running water and dry it carefully

By oral route:

Posology

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

Method of administration:

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

Dilute the content of the ampoule in a glass containing a little water (the equivalent of a dessert spoon), to be taken during a meal once a day.

- **Adults and Children aged more than 5 years old:**

Dilute the content of the ampoule in a glass containing a little water (the equivalent of a dessert spoon) to be taken during a meal twice a day.

Treatment duration

Always respect the dosage indicated by your doctor. If in doubt, consult your doctor or pharmacist.

If you take more ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation than you should:

Immediately consult your doctor or pharmacist.

If you forget to take ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation:

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 stomachs ache following oral administration.

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

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 outer carton. 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, 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation contains

- The active substances are:

Sodium sulphide nonahydrate.....	4.0 mg
<i>Saccharomyces cerevisiae</i> yeast.....	50.0 mg

per a 10-ml ampoule.

- The other ingredients are:

Saccharin sodium, polysorbate 80, Neroli flavor*, sodium chloride, purified water

* Composition of Neroli flavor: essential oils of Citrum Aurantium and sweet orange, geraniol, terpineol, linalol, methyl anthranilate, phenylethyl alcohol, geranyl acetate.

What ACTISOUFRE, 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation looks like and contents of the pack

This medicine is an oral or nasal suspension in a 10-mL ampoule. Box of 30 ampoules with 1 dropper vial.

Marketing Authorisation Holder:

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

Manufacturer:

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