

PACKAGE LEAFLET

ACTISOUFRE 4 mg/50 mg per 10 ml, oral suspension or suspension for nasal instillation
Sodium sulphide nonahydrate, *Saccharomyces cerevisiae*

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 you have any doubt, ask your doctor or pharmacist for more information.

- Keep this leaflet, you may need to read it again.

- If you need further information or advice, ask your pharmacist.

If the symptoms get worse or persist, consult your doctor.

In this leaflet:

1. WHAT IS ACTISOUFRE 4mg / 50 ml, oral suspension or suspension for nasal instillation AND WHEN IS IT USED FOR?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING ACTISOUFRE 4mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?
3. HOW TO USE ACTISOUFRE 4mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
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6. FURTHER INFORMATION

1. WHAT IS ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation AND WHEN IS IT USED FOR?

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

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

2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation?

Never take ACTISOUFRE 4 mg / 50 mg per 10 mL, oral suspension or suspension for nasal instillation in the following case:

- allergy to sulphur.

If in doubt, it is essential to ask your doctor or pharmacist for advice.

Take special care with ACTISOUFRE, 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation:

For oral administration and in case of a low-salt diet, take into account the sodium intake, which is about 37 mg per ampoule.

If in doubt, ask your doctor or pharmacist for advice.

Taking or using other medicines:

In order to prevent potential interactions between several medicines, always inform your doctor or pharmacist of any other ongoing treatment.

Always 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

In general, if you are pregnant or breast-feeding, always ask your doctor or pharmacist for advice before using a medicine.

List of excipients with known effect: sodium (in the form of sodium chloride and saccharin sodium).

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

By the nasal route:

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.

If you have the impression that the effect of ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation, is too strong or too weak: consult your doctor or pharmacist.

Method of administration:

- 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.
- When the ampoule is opened, the odour shows 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.
- 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.

By the oral route:

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

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

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

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.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

Like all medicines, **ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation**, can cause side effects, although not everybody gets them

- Potential stomach ache following oral administration.

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.ansm.sante.fr. By reporting the adverse events, you contribute to supply more information on the medicine safety.

5. HOW TO STORE ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation ?

Keep out of the reach and sight of children.

Do not use ACTISOUFRE 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation after the expiry date which is stated on the box.

Store in the original outer packaging.

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

6. FURTHER INFORMATION

What does ACTISOUFRE, 4 mg / 50 mg per 10 ml, oral suspension or suspension for nasal instillation, contain?

The active substances are:

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

per a 10-ml ampoule.

* Yeast

The other constituents are:

Saccharin sodium, polysorbate 80, Neroli flavor*, sodium chloride, purified water q.s.

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

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

This medicine is an oral or nasal suspension in a 10-mL ampoule.

Marketing Authorisation Holder/Operating company:

LABORATOIRES GRIMBERG - 19 rue Poliveau - 75005 Paris – France

Manufacturer:

LABORATOIRES GRIMBERG - Z.A. des Boutries - 5 rue Vermont - 78700 Conflans Sainte Honorine - France

This leaflet was last approved on 14th March 2014.