

Características Técnicas



IberGRAF
OFFSET
GRÁFICOS ANDREU COLL S.L.

Cliente: LAB. ALDO-UNION, S.L.

H.P.: 11800

Producto: NASOALDO (AFRICA FRANCESA)

Código: 510515/A-20

Anula a: NUEVO

Papel: PRIMABRITE

Gramaje: 40 g

C. Barras: 674

Medidas: 170 x 620 mm

Medidas Plegado: 170 x 310 mm

Tipografía: TRAZADA

Colores: 1+1 NEGRO

C.I.: 83246

Fecha: 03 / 07 / 2020

A corregir
Aprobado

Fecha y Firma

Package leaflet: information for the user
NASOALDO 50 micrograms/spray nasal spray suspension

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What NASOALDO is and what it is used for
2. What you need to know before you use NASOALDO
3. How to take NASOALDO
4. Possible side effects
5. How to store NASOALDO
6. Contents of the pack and other information

1. What NASOALDO is and what it is used for

What is NASOALDO?

NASOALDO 50 micrograms/actuation nasal spray, suspension contains mometasone furoate, a medicine that belongs to a group of medicines called corticosteroids. When mometasone furoate is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

What is NASOALDO used for?

Hayfever and perennial rhinitis
NASOALDO is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 and older. Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things, including house dust mites, animal hair (or dander), feathers and certain foods. NASOALDO reduces the swelling and irritation in your nose, thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial rhinitis.

Nasal polyps

NASOALDO is used to treat nasal polyps in adults aged 18 and over. Nasal polyps are small formations in the mucosa of the nose and usually affect both nostrils. NASOALDO reduces inflammation in the nose, causing polyps to gradually reduce, thereby relieving a blocked-up nose that can make it difficult to breathe through your nose.

2. What you need to know before you use NASOALDO

Do not use NASOALDO

- If you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- If you have an untreated infection in your nose. Use of NASOALDO during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- If you have recently had an operation on your nose or you have injured your nose. You should not use the nasal spray until your nose has healed.

Warnings and precautions

- Tell your doctor or pharmacist before using NASOALDO:
 - if you are currently taking or have ever had tuberculosis,
 - if you have any other type of infection,
 - if you are taking other corticosteroid medicines, either by mouth or by injection,
 - if you have cystic fibrosis (a multi-organ genetic disease that mainly affects the lungs and the digestive system).

While you are using NASOALDO, talk to your doctor

- If your immune system is not functioning well (if you have difficulty in fighting infection) and you come into contact with anyone with measles or chickenpox. You should avoid coming into contact with anyone who has these infections.
- If you have an infection of the nose or throat.
- If you are using the medicine for several months or longer.
- If you have persistent irritation to the nose or throat.

Talk to your doctor if you develop blurred vision or other problems with your sight.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

If your eyes are itching or irritated, your doctor may recommend that you use other treatments with NASOALDO.

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as slowed growth rate in children. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

Other medicines and NASOALDO

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using mometasone furoate. A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, muscle weakness and depression. You may also develop other allergies, such as watery eyes, itching eyes or red patches in skin and itchy skin. If you develop any of these side effects, you should see your doctor. Some medicines may increase the effects of Nasoaldo 50 micrograms/actuation nasal spray, suspension and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV, ritonavir, cobicistat).

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 using this medicine. There is little or no information on the use of mometasone furoate in pregnant women. It is not known if mometasone furoate is found in breast milk.

Driving and using machines

There is no known information on the effect of NASOALDO on the ability to drive or use machinery.

NASOALDO contains benzalkonium chloride

NASOALDO contains benzalkonium chloride which may cause nasal irritation.

3. How to use NASOALDO

Always use this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than your doctor tells you to.

Treatment of hayfever and perennial rhinitis

Use in adults and children over 12 years old

The usual dose is two sprays into each nostril once a day.
- Once your symptoms are under control, your doctor may advise you to decrease the dose.
- If you do not start to feel any better, you should see your doctor and he or she may tell you to increase the dose to the maximum daily dose of four sprays into each nostril once a day.

Use in children aged 3 to 11 years

The usual dose is one spray into each nostril once a day.
If you or your child suffer badly from hayfever, your doctor may tell you to start taking NASOALDO before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring. By the end of the pollen season, your hayfever symptoms should have improved and the treatment may no longer be necessary.

Nasal polyps

Use in adults over 18 years old

The usual starting dose is two sprays into each nostril once a day.
- If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice a day. Once symptoms are under control, your doctor may advise you to decrease your dose.
- If there is no improvement in symptoms after 5 to 6 weeks of twice daily administration, you should contact your doctor.

Method of administration

Preparing your nasal spray for use
NASOALDO has a dust cap which protects the nozzle and keeps it clean.

Remember to take this off before using the spray and to replace it after use.

If you are using the spray for the first time you need to "prime" the bottle by pumping the spray 10 times until a fine mist is produced.

1. First, gently shake the bottle.
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle.

Do not pierce the nasal applicator.

3. Point the nozzle away from you and then press down with your fingers to pump the spray 10 times until a fine mist is produced.

If you have not used the spray for 14 days or more, you need to "re-prime" the bottle by pumping the spray twice until a fine mist is produced.

How to use your nasal spray

1. Gently shake the bottle and remove the dust cap (Figure 1).
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown. (Figure 2). Tilt your head forward slightly, keeping the bottle upright.
4. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe through your mouth.
7. Repeat steps 3 to 5 for the other nostril. (Figure 3).

After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.

Cleaning your nasal spray

- It is important to clean your nasal spray regularly, otherwise it may not work properly.
- Remove the dust cap and gently pull off the nozzle.
- Wash the nozzle and dust cap in warm water and then rinse under a running tap.
- Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.
- Allow the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

If you take more NASOALDO than you should

Tell your doctor if you accidentally take more than you should.

If you use steroids for a long time or in large amounts they may, rarely, affect some of your hormones. In children this may affect growth and development.

If you forget to take NASOALDO

If you forget to take your nasal spray at the right time, take it as soon as you remember, then carry on with the normal frequency of administration. Do not take a double dose to make up for a forgotten dose.

If you stop the treatment with NASOALDO

In some patients NASOALDO should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. It is very important that you use your nasal spray regularly.

Do not stop your treatment even if you feel better unless told to do so by your doctor. 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. Immediate hypersensitivity (allergic) reactions may occur after use of this medicine. These reactions may be severe. You should stop taking NASOALDO and get immediate medical help if you experience symptoms such as:

- swollen face, tongue or throat
- trouble swallowing
- hives
- shortness of breath or difficulty breathing

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

Other side effects

Most people do not have any problems after using the nasal spray. However, some people, after using mometasone furoate or other corticosteroid nasal sprays, may find that they suffer from:

- Common side effects (can affect up to 1 in 10 people)
 - headache
 - sneezing
 - nose bleeds (very common [may affect more than 1 in 10 people] in people with nasal polyps taking two sprays of mometasone furoate in each nostril twice a day.)
 - sore nose or throat
 - itching in the nose
 - respiratory tract infection

Not known frequency cannot be estimated from the available data

- increase in eye pressure (glaucoma) and/or cataracts causing visual disturbances
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or fatigue
- blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NASOALDO

Keep this medicine out of the reach and sight of children. Do not store above 30°C. Do not freeze. Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month. The spray should be used within 2 months of first opening. Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NASOALDO contains

The active substance is mometasone furoate. Each spray contains 50 micrograms of mometasone furoate, as monohydrate. The other ingredients are disintegrant cellulose (microcrystalline cellulose and sodium carmellose), glycerol, sodium citrate, anhydrous acetic acid, benzalkonium chloride, poloxamer 181 and purified water.

What NASOALDO looks like and contents of the pack

NASOALDO is a nasal spray suspension. It comes in an opaque white 140-spray plastic bottle equipped with a metering spray pump, a nasal adapter and a dust cap.

Marketing Authorisation Holder and Manufacturer

Laboratorio Alco-Union, S.L.
Barones de Mafá, 70
08950 Esplugues de Llobregat
Barcelona - Spain

This leaflet was last revised in 10/2017



Figure 1



Figure 2



Figure 3

