PATIENT INFORMATION LEAFLET

NEXOMIST

SCHEDULING STATUS:

S2

NEXOMIST 50 µg per spray, nasal spray

mometasone furoate

Read all of this leaflet carefully because it contains important information for you

NEXOMIST is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NEXOMIST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NEXOMIST with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What NEXOMIST is and what it is used for

NEXOMIST is an aqueous suspension of mometasone furoate 0,05 % *m/v*. Each metered spray delivered by the nasal adaptor contains 50 µg mometasone furoate.

NEXOMIST is indicated for use in adults, adolescents and children between the ages of 2 and 11 years to treat the symptoms of seasonal or perennial allergic rhinitis. In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with NEXOMIST is recommended prior to the anticipated start of the pollen season.

2. What you need to know before you use NEXOMIST

Do not take NEXOMIST if you are:

- hypersensitivity (allergic) to mometasone furoate or any of the other ingredients of NEXOMIST (listed in **section 6**).
- Pregnancy and lactation (see **Pregnancy, breastfeeding and fertility**)
- Child under 2 years, as safety and efficacy have not been demonstrated.

Warnings and Precautions

Take special care with NEXOMIST:

NEXOMIST should not be used in the presence of untreated localised infection involving the nasal mucosa. Because of the inhibitory effect of corticosteroids on wound healing, patients who have experience recent nasal surgery or trauma should not use NEXOMIST until healing have occurred.

Patients using NEXOMIST over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localised fungal infection of the nose or pharynx develops, discontinuation of NEXOMIST or appropriate treatment may be required.

Persistence of nasopharyngeal irritation may be an indication for discontinuing NEXOMIST.

NEXOMIST should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacteria, systemic viral infections or ocular herpes simplex.

Patients who are transferred from long-term administration of systemically active corticosteroids to NEXOMIST require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of hypopituitary adrenal (HPA)-axis function. If these patients exhibit signs and symptoms of adrenal insufficiency, systemic corticosteroid administration should be resumed, and other modes of therapy and appropriate measures instituted.

During transfer from systemic corticosteroid to NEXOMIST, some patients may experience symptoms of withdrawal from systemically active corticosteroids (e.g. joint and / or muscular pain, lassitude and depression initially) despite relief from nasal symptoms and will require encouragement to continue NEXOMIST therapy.
Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously supressed by systemic corticosteroid therapy.

Patients receiving NEXOMIST who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g. chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs. Following the use of intranasal aerosolised, instances of nasal septum perforation or increase intraocular pressure have been reported very rarely.

Treatment with higher than recommended doses may result in hypercortism and clinically significant adrenal suppression. In these cases, additional systemic corticosteroid cover should be considered during periods of stress and elective surgery.

After using nasal corticosteroids sprays, you may experience nasal perforation or increased eye pressure.

If you experience blurred vision or visual disturbances, contact your doctor.

Other medicines and NEXOMIST

See **section 2**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

Tell your healthcare professional if you are taking ketoconazole (medicine used to treat fungal infections), itraconazole (medicine used to treat fungal infections), clarithromycin (medicine used to treat bacterial infections), ritonavir (medicine used to treat HIV), these may cause increased side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking NEXOMIST.

NEXOMIST contains benzalkonium chloride. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use NEXOMIST

Do not share medicines prescribed for you with any other person.

Always take NEXOMIST exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

After initial priming of the NEXOMIST pump (usually 6 or 7 actuations, until a uniform spray is observed), each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 µg mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed before next use. No priming subsequent to initial priming is required with regular use.

Shake container well before each use.

Adults and adolescents:

The usual recommended dose for prophylaxis and treatment is two sprays (50 µg/spray) into each nostril once daily (total dose 200 µg). Once symptoms are controlled, dose reduction to one spray into each nostril (total dose 100 µg) may be effective in some patients for maintenance. If symptoms are inadequately controlled, the dose may be increased to four sprays into each nostril (total dose 400 µg). Dose reduction is recommended following control of symptoms.

Children between the ages of 2 and 11 years:

The usual recommended dose is one spray (50 µg / spray) in each nostril daily (total dose 100 µg).



Bottle with Metered-Dose Atomising Pump | Nozzle | Dust Cap

Important:

1. Use NEXOMIST as directed by your doctor. Do not exceed the recommended dose.
2. It takes a few days for this medicine to work; hence it is very important that you use it

regularly. Do not stop treatment even if you feel better unless told to do so by your doctor.

3. This medicine has been specially recommended by your doctor for you. Do not allow any other person to use it.
4. Keep NEXOMIST out of reach of children.
5. Protect NEXOMIST from light. Use within two months of opening.

How to use NEXOMIST:

Before using:

1. Shake the bottle gently, then remove the dust cap.
2. Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.

3. 

Before using NEXOMIST: for the first time or if you have not used it for a longer period, follow the instructions given below:

With the nozzle pointing away from you, press several times

as shown until a fine uniform mist comes out of the nozzle.



4. Blow your nose gently.



5. Close one nostril and put the nozzle in the other nostril as shown. Tilt your head slightly forward keeping the nozzle in the upright position.
6. Start to breathe in through your nose and while breathing in press down with your fingers once to release a spray.



7. Breathe out through your mouth. Repeat steps 6 & 7 to inhale a second spray (if indicated).



8. Repeat steps 5, 6 and 7 for the other nostril.



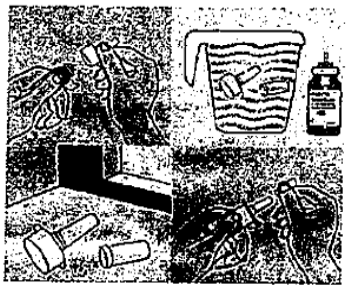
9. After use

Wipe the nozzle with a clean cloth and replace the dust cap.

Cleansing:

NEXOMIST container nozzle should be cleaned at least once a week.

To do this:



1. Push the nozzle upwards to detach from the bottle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place.

3. Replace the nozzle and dust cap.
4. If the nozzle becomes blocked, remove as above and soak in warm water. Rinse under a cold tap, allow to dry and refit. Do not use a pin or other sharp object to unblock the nozzle.

If you take more NEXOMIST than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

If you forget to use NEXOMIST

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible Side Effects

NEXOMIST can have side effects

Not all side effects reported for NEXOMIST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEXOMIST, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any of the following:

Body as a whole:

Less frequent: Hypersensitivity reactions (including bronchospasm and dyspnea), angloedema and anaphylaxis have been reported after intranasal administration.

Gastrointestinal disorders:

Less frequent: Nausea.

Haematological and Lymphatic system disorders:

Less Frequent: Treatment-related local adverse events reported in clinical studies include epistaxis (i.e. frank bleeding, blood-tinged mucus and blood flecks.)

Epistaxis was generally self-limiting and mild in severity.

Central nervous system disorders:

Frequent: Dizziness, headache.

Respiratory system disorders:

Less frequent: Rhinitis, sinusitis, cough, nasal septum irritation, rhinorrhea, pharyngitis, nasal burning, nasal irritation and epistaxis.

Skin and appendages disorders:

Less frequent: Rash.

Special senses disorders:

Less frequent: Taste perversions, conjunctivitis, dry eyes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of NEXOMIST.

5. How to store NEXOMIST

Store at or below 25 °C.

Protect from light. Use within 2 months of opening.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What NEXOMIST contains

The active substance is mometasone furoate.

The other ingredients are glycerol, microcrystalline cellulose and carmillose sodium (Avicel CL 611), anhydrous citric acid, polysorbate 80, benzalkonium chloride, sodium citrate dihydrate water for injection.

What NEXOMIST looks like and contents of the pack

NEXOMIST is a white to off-white coloured homogeneous, re-dispersible suspension.

NEXOMIST aqueous nasal spray is supplied in a 20 mL white opaque HDPE vial providing 140 actuations, with a net fill weight of 18,0 g. Each bottle is fitted with a white, metered atomising pump, white nasal adaptor and a translucent dust cap for the nozzle, packed in a carton.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9, Parc du Cap

Mispel Street

Bellville

7530, R.S.A.

Customer Care: 080 222 6662

This leaflet was revised in

17 August 2022

Registration number

A 38/21.5.1/0341

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.

Namibia: NS2 10/14.4.1/0519

Botswana: S2 BOT0901566

References

1. SAHPRA-approved PI, Nasonex aqueous nasal spray, by MSD (Pty) Ltd, dated 30 October 1998, Date PI amended 17 February 2017
2. Current SAHPRA Guideline for Professional Information for Human Medicines (Categories A and D), dated July 2019.