PACKAGE INSERT FOR NEXOMIST

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

NEXOMIST (Aqueous nasal spray)

COMPOSITION:

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

Preservatives: Benzalkonium chloride 0,01 % *w/w*

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues

PHARMACOLOGICAL ACTION:

Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory, antipruritic and vasoconstrictory properties.

INDICATIONS:

NEXOMIST is indicated to treat the symptoms of seasonal or perennial allergic rhinitis in adults, adolescents and children between the ages of 2 and 11 years.

It is recommended that prophylactic treatment with **NEXOMIST** is initiated prior to the anticipated start of the pollen season in those patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis.

CONTRA-INDICATIONS:

NEXOMIST is contra-indicated in:

- Patients with known hypersensitivity to any of the ingredients in **NEXOMIST**.
- Pregnancy and lactation (see **"PREGNANCY AND LACTATION"**).
- Children under 2 years, as safety and efficacy have not been demonstrated.

WARNINGS:

Patients intolerant of benzalkonium chloride may be intolerant to **NEXOMIST** since it contains this substance as preservative.

INTERACTIONS:

Co-administration of **NEXOMIST** with loratadine did not appear to affect plasma concentrations of loratadine or its major metabolite. Mometasone furoate plasma concentrations could not be detected. Combination therapy is well tolerated.

PREGNANCY AND LACTATION:

Safe use of **NEXOMIST** in pregnant and lactating women has not been established (see **"CONTRA-INDICATIONS"**).

DOSAGE AND DIRECTIONS FOR USE:

Before use, **NEXOMIST** nasal spray should be primed. Priming is achieved by releasing 6 or 7 actuations into the air, until a uniform spray is observed. After priming, each actuation delivers anhydrous mometasone furoate equivalent to 50 µg mometasone furoate. Repriming is required in all instances where the spray pump has not been used for 14 days or longer. If the spray pump is used regularly, no priming subsequent to initial priming is required.

Shake container well before each use.

Adults and adolescents:

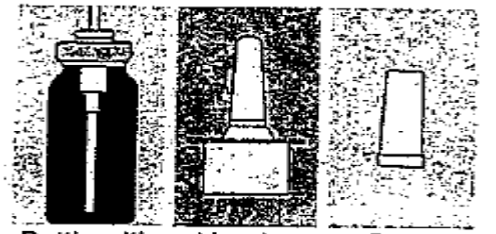
For both the treatment and prophylaxis of allergic rhinitis the usual recommended dose is two sprays (50 µg/spray) into each nostril once daily equal to a total dose of 200 µg per day. For maintenance therapy, once symptoms have been brought under control, a dose reduction to one spray into each nostril (total dose 100 µg per day) may be effective in some patients.

If symptoms are not adequately controlled on a total dose of 200 µg per day, the dose may be increased to 4 sprays into each nostril (total dose 400 µg per day). Once symptoms are under control, it is recommended that the dose be reduced.

Children between the ages of 2 and 11 years:

In this population the usual recommended dose is one spray (50 µg/spray)

into each nostril once daily equal to a total dose of 100 µg per day.



Important:

1. Use **NEXOMIST** as per your doctor's directions. The recommended dose should not be exceeded.
2. It is very important that you use **NEXOMIST** regularly, since it takes a number of days for it to work. You should not stop taking **NEXOMIST**, even if you feel better, unless your doctor has instructed you to do so.
3. Your doctor has recommended **NEXOMIST** specially for you. You should 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 longer than 14 days, 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. Breath 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.



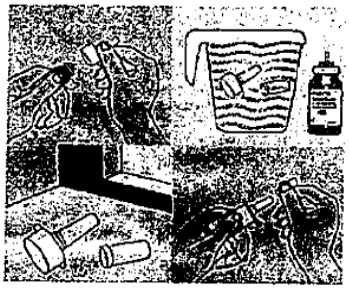
9. After use

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

Cleansing:

NEXOMIST 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.**

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

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 mild and self-limiting.

Neuropsychiatric system disorders:

Frequent: Dizziness, headache.

Disorders of the special senses:

Less frequent: Taste perversions, conjunctivitis, dry eyes.

Respiratory system disorders:

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

Gastrointestinal system disorders:

Less frequent: Nausea.

Skin and subcutaneous tissue disorders:

Less frequent: Rash.

General disorders:

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

Special Precautions:

Patients should not administer **NEXOMIST** in the presence of untreated localised infection that involves the nasal mucosa.

After recent nasal surgery or trauma, patients should postpone the use of **NEXOMIST** until healing has occurred, because of the inhibitory effect of corticosteroids on wound healing.

Periodic examination to detect possible changes in the nasal mucosa is required in patients who use **NEXOMIST** over several months or longer. It may be necessary to discontinue **NEXOMIST** or to institute appropriate treatment if a localised fungal infection of the nose or pharynx develops. **NEXOMIST** may have to be discontinued if nasopharyngeal irritation persists.

In the presence of active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex, **NEXOMIST** should be administered with caution, if at all.

Patients should be carefully monitored following transferral from long-term treatment with systemically active corticosteroids to **NEXOMIST**. Adrenal insufficiency may result from systemic corticosteroid withdrawal and may persist for a number of months until recovery of hypothalamic-pituitary-adrenal (HPA) axis function. Should signs and symptoms of adrenal insufficiency develop, systemic corticosteroid treatment must be resumed and other modes of therapy and appropriate measures instituted.

Some patients may develop symptoms of withdrawal from systemically active corticosteroids (including depression initially, lassitude and joint and/or muscular pain) while being transferred from systemic corticosteroids to **NEXOMIST**. This may occur despite relief from nasal symptoms and patients should be encouraged to continue **NEXOMIST** therapy. Pre-existing allergic conditions, such as eczema and allergic conjunctivitis, suppressed by

systemic corticosteroid therapy, may also become unmasked during such transfer.

Potentially immunosuppressed patients for whom **NEXOMIST** is prescribed should be warned of the risk of exposure to certain infections (e.g., measles, chickenpox) as well as of the importance of obtaining medical advice following such exposure.

There have been very rare reports of instances of nasal septum perforation or increased intraocular pressure following the use of intranasal aerosolised **NEXOMIST**.

Hypercorticism and clinically significant adrenal suppression may occur if higher than recommended doses are used. In such instances it may become necessary to consider additional systemic corticosteroid cover during periods of stress or elective surgery.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **"SIDE EFFECTS AND SPECIAL PRECAUTIONS"**. Due to the low systemic bioavailability of mometasone, it is unlikely that overdose will require any therapy other than observation, followed by initiation of the appropriate prescribed dosage. If excessive doses of **NEXOMIST** is inhaled or taken orally, it may lead to suppression of hypothalamic-pituitary-adrenal (HPA) axis function.

IDENTIFICATION:

A white to off-white homogeneous, redispersible suspension.

PRESENTATION:

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.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from light. Use within 2 months of opening.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

A38/21.5.1/0341

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD.

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

11 August 2006