

NASEHALER (Mometasone Furoate Nasal Spray 50mcg)

Mometasone Furoate (50mcg/actuation)

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What NASEHALER is used for

NASEHALER Aqueous Nasal Spray contains mometasone furoate, one of a group of medicines called corticosteroids.

NASEHALER is used in adult and children 3 years of age and older to treat the symptoms of seasonal or perennial rhinitis.

How NASEHALER works

When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and a blocked up or runny nose.

Before you use NASEHALER

When you must not use it

- If you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of NASEHALER.
- If you have an infection in your nose. You should wait until the infection is resolved before you start using the nasal spray.
- If you have bleeding tendency or recurring nose bleeds.
- If you have recently had an operation on your nose or you have injured your nose. You should wait until it has healed before you start using the nasal spray.

Before you start to use it

Tell your doctor or pharmacist about any medical problems, such as

- If you have or have ever had tuberculosis
- If you have herpes simplex (virus) infection of the eye
- If you have any other type of infection
- If you are taking other corticosteroid medicines, either by mouth or by injection
- If you had recent nasal surgery or trauma.

Discuss them with your doctor before taking NASEHALER.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 NASEHALER. 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, weakness and depression. If these occur you should inform your doctor who will advise about continuing use of your nasal spray. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects and you are worried, you should see your doctor.

Some medicines may increase the effects of NASEHALER and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

Pregnancy and breast-feeding

You should not use NASEHALER if you are pregnant unless your doctor has told you to. Tell your doctor if you are pregnant before you start using this medicine. You should not breast feed when you are using this medicine unless your doctor has told you to.

How to use NASEHALER

How much to use

Always use NASEHALER exactly as your doctor 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.

Adults and children 12 years of age and older:

The usual dose is two sprays into each nostril once a day.

- Once your symptoms are under control, your doctor may advise you to only spray once into each nostril once a day.
- If you do not start to feel any better, you should see your doctor and he may tell you to increase the dose to the maximum daily dose of four sprays into each nostril once a day. Once your symptoms are controlled your doctor may advise you to reduce the dose

Children aged 3 to 11 years: The usual dose is one spray into each nostril once daily.

Long term use of nasal steroids at high doses may cause slowing of growth in children. Your doctor may check your child's height at intervals during treatment and reduce the dose if any effects are seen.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Do not use the spray for longer than your doctor tells you to.

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How should I use Nasehaler?

Parts of the Nasal Spray



Using your Nasal Spray correctly

Before use:



Shake the bottle gently and then remove the protective dust cap.

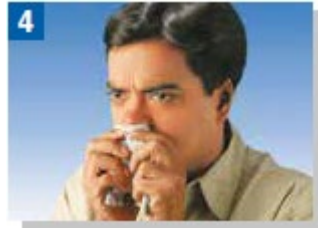


Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.

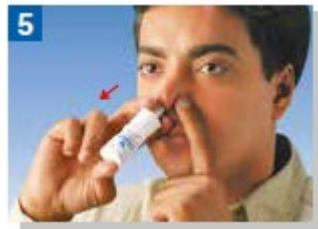


If using for the first time or if you have not used it for a week or more, test the spray: with nozzle pointing away from you, press down several times as shown until a fine mist comes out of the nozzle.

During use:



Blow your nose gently.



Close one nostril as shown and put the nozzle in the other nostril.

6 Start to breath in through you nose and WHILE BREATHING IN press down with your fingers ONCE to release a spray.



Breath out through your mouth, Repeat steps 6 and 7 to inhale a second spray.

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

After use:



Wipe the nozzle with a clean handkerchief / tissue and replace the protective dust cap.

Cleaning your Nasal Spray

Your nasal spray should be cleaned at least once a week.

To do this:



Push the nozzle upwards to detach from the bottle.



Wash the nozzle and the dust cap in warm water.



Shake off excess water and allow nozzle and cap to dry at room temperature before refitting into the bottle.

Note:

If the nozzle becomes blocked, remove it as shown and soak in warm water. Rinse the nozzle under running cold water from a tap. Allow the nozzle to dry before refitting it to the bottle.

DO NOT USE A PIN OR A SHARP OBJECT TO UNBLOCK THE NOZZLE AS THIS WILL DESTROY SPRAY MECHANISM.

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If you forget to use it

If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before.

Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

Tell your doctor if you accidentally use more than you were told.

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 stop using NASEHALER

In some patients NASEHALER should begin to relieve symptoms 12 hours after the first dose. 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 product, ask your doctor or pharmacist.

While you are using NASEHALER

Things you must do

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you plan to have or have had a recent nasal surgery or trauma.

Contact your doctor if you experience blurred vision or other visual disturbances.

Things you must not do

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

NASEHALER is for intranasal use only. Avoid getting it into your eyes. Do not use it to treat anything other than the condition for which it was prescribed.

Things to be careful of

While using NASEHALER, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who is suffering from these infections.

Side Effects

Like all medicines, NASEHALER can cause side effects, although not everybody gets them.

Rarely, immediate hypersensitivity (allergic) reactions may occur after use of this product. Very rarely, these reactions may be severe. If you have any wheezing or have trouble breathing, get immediate medical help.

In very rare cases, treatment with corticosteroid nasal sprays like NASEHALER has led to an increase in pressure in the eye (glaucoma), causing visual disturbances and damage to the partition in the nose which separates the nostrils. Contact your doctor if you notice any of these side effects.

Other side effects

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

- headache
- sneezing
- nose bleeds
- sore nose or throat
- alterations in taste or smell which may occur very rarely.
- blurred vision

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side effects, such as growth reduction 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.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of NASEHALER

Storage

- Keep out of the reach and sight of children.
- Store below 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

NASEHALER aqueous nasal spray is a white to off white coloured, homogenous dispersible suspension filled in 20 mL white opaque HDPE vial crimped with nasal spray assembly.

Ingredients

Active ingredients:

Mometasone Furoate
Monohydrate equivalent to
Mometasone Furoate 50 mcg

Inactive ingredients:

Benzalkonium Chloride
Solution (10%),
Microcrystalline cellulose +
carmellose sodium, Citric Acid
Monohydrate, Polysorbate 80,
Glycerol, Sodium Citrate
Dihydrate, Water for Injection

Pack Size

Each carton contains 1 unit of
Nasehaler of 140 sprays,

NASEHALER (Mometasone Furoate Nasal Spray 50mcg)

Mometasone Furoate (50mcg/actuation)

containing 50 mcg
mometasone furoate per
actuation.

MAL Number

MAL07021392AZ

Manufacturer

CIPLA LTD
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Product Registration Holder

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31 December 2023

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