

ELONIDE NASAL SPRAY

Mometasone Furoate (50mcg/dose)

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This leaflet answers some common questions about Elonide. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may want to read it again.

What Elonide is used for

Elonide is sprayed into the nose to help relieve symptoms that may occur with hayfever or other year-round allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing.

Your doctor may have prescribed it for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that this medicine is addictive.

How Elonide works

Elonide contains the active ingredient Mometasone Furoate. This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Elonide

When you must not use it

Do not use the medicine if:

1. You have an allergy to:
 - any medicine containing Mometasone Furoate
 - any of the ingredients listed at the end of this leaflet
2. You have localised fungal infection or persistence irritation of the nose or throat.

Do not use it after the expiry date (EXP) printed on the pack or if the packaging is torn or shows sign of tampering.

If you are not sure whether you should start taking this medicine, contact your doctor.

Before you start to use it

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- A history of tuberculosis, inactive or active tuberculosis (bacterial infection that mainly affects the lung).
- If you have untreated infection including fungus, bacteria, and virus.

If you have used at high doses for long periods of time, Corticosteroid nasal sprays may cause certain side-effects, such as growth retardation (slowed growth rate) in children. It

is recommended that the height of children is regularly monitored.

Tell your doctor or pharmacist if you are taking other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection.

If you want to change from other corticosteroids to ELONIDE Nasal Spray, you may experience symptoms of withdrawal from systemically active corticosteroids (e.g. joint and/or muscular pain, tiredness, and depression initially). You need to continue to use Elonide even these conditions occur. Such transfer may also unmask pre-existing allergic conditions, such as allergic eye inflammation and eczema, previously suppressed by oral corticosteroid therapy.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Pregnancy and lactation

Tell your doctor before taking this medicine if you are pregnant or intend to become pregnant or breastfeeding.

Your doctor will discuss the possible risks and benefits of using this medicine during pregnancy and breastfeeding.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

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How to use Elonide

Follow all directions given to you by your doctor or pharmacist carefully and do not use more than the recommended dose.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use

Adults (including the elderly) and children 12 years of age and older:

Two sprays into each nostril once daily.

Children 3 to 11 years of age:

One spray into each nostril once daily.

Each actuation of the spray pump delivers the equivalent of 50 microgram of Mometasone Furoate. The volumes of the containers are sufficient to deliver the labelled 60 sprays, or 140 sprays.

Your doctor may change this dosage, depending on your response to this medicine.

About your nasal spray

Your nasal spray 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 have not used the pump for 14 days or more reprime by pumping once into the air before use. The nozzle should be pointed away while doing this.

It is important to clean the nozzle at least once a week regularly; otherwise, it may not work properly.

How to clean it:

Remove the dust cap and gently pull off the nozzle. Soak the dust- cap and spray nozzle in warm water for a few minutes. Rinse under a cold running tap. Shake or tap off the excess water and allow air-drying. Re-fix the spray nozzles. Prime the unit as necessary until a fine mist is produced and use as normal (See How to use it).

How to use it:

1. Blow the nose gently to clear nostrils.
2. Shake the bottle gently.
3. For first time use, hold the bottle upright and fill the pump by pressing the nozzle downwards and releasing it 5 times, until a fine spray is produced.
4. Close one nostril with finger. Hold the bottle upright and insert the nostril as far as is comfortable. Whilst breathing in gently through the nose with mouth closed, press the bottle upwards once to deliver one spray.
5. Breathe out through the mouth.
6. Repeat steps 4 and 5 for the other nostril.
7. For individuals aged 12 years and older, steps 4, 5 and 6 should be repeated once more to achieve the recommended dosage of 2 sprays into each nostril.
8. To keep the spray nozzle clean, wipe it carefully with a clean tissue after each use and replace the cap.
9. If the spray does not work and it may be blocked, clean it as follows. (See How to clean it). NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

When to use it

As instructed by your doctor. Do not use more frequently than instructed.

How long to use it

Your doctor will determine the length of treatment.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to use your medicines as you would normally.

Do not use a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

Immediately telephone your doctor, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

While you are using Elonide

Things you must do

If you become pregnant while you are using this medicine, tell your doctor.

Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using this medicine.

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If you are going to have surgery, tell the surgeon or anesthetists that you are using this medicine.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

This medicine generally does not cause any problems with your ability to drive a car or operate machinery.

If you have a lower resistance to infection, avoid coming into contact with anyone who has measles or chickenpox especially while you are using cortisone-type medicines. Tell your doctor if you do.

Side effects

The doctor will decide whether any change in your treatment is needed.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are elderly, you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most people do not have any problems after using the nasal spray. However, a few people may find that they suffer from one or more of the following:

- headache
- severe or ongoing nose bleed

- Sore throat or sores inside the nose after using this medicine. These symptoms are consistent with the use of corticosteroid nasal sprays.

If you develop a rash, wheezing or breathlessness, stop using the nasal spray, as you may be allergic to it and contact your doctor immediately.

Other side effects not listed above may also occur in some individual. Tell your doctor if you notice anything that is making you feel unwell.

Long-term use of corticosteroid sprays may be associated with other side effects such as nose lining changes. Your doctor will monitor your health if you are using Elonide for extended periods of time.

Following to the use of intranasal corticosteroids, instances of nasal septum perforation (damage to the partition in the nose which separates the nostrils) or increased eye pressure has been reported very rarely.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Elonide

Storage

Store below 30 °C.

Keep out of reach of children.

Keep bottle in upright position.

Disposal

Dispose the medicine after the expiry date.

Consult your pharmacist on how to safely dispose of any medicines no longer required.

Product description

What it looks like

An opaque off-white slightly viscous suspension.

Elonide is packed in a 10ml or 20ml plastic spray bottle.

Ingredients

Active ingredients:

Mometasone Furoate 50mcg/dose

Inactive ingredients:

Benzalkonium Chloride,
Polysorbate 80, Sodium Citrate,
Citrate Acid Anhydrous, Glycerin,
Microcrystalline Cellulose,
Carboxymethylcellulose Sodium
and Purified Water.

MAL number

MAL12015004AZ

Manufacturer:

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohd. 6,
Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
Malaysia.

Product Registration Holder:

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