

Eltair™ Aqueous Nasal Spray

Budesonide 50 µg/dose Aqueous Nasal Spray

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ELTAIR.

It does not contain all the available information on this medicine.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ELTAIR against the benefits it is expected to have for you.

Keep this leaflet with the medicine, you may need to read it again.

What is it used for

ELTAIR contains the active ingredient budesonide, which belongs to a group of medicines known as **corticosteroids**.

ELTAIR is used for:

- The short-term (3-6 months) treatment and prevention of the symptoms of seasonal (hay fever) and non-seasonal allergic reaction of the nasal mucus lining.

Or as prescribed by your doctor

- The treatment of vasomotor rhinitis – a non-allergic reaction brought on by mild chilling, fatigue, anger and anxiety.
- The symptomatic relief of nasal polyposis (a protruding growth of the nasal mucous lining)

Your doctor may have prescribed ELTAIR for another reason.

If you have any concerns about taking this medicine or would like to know why ELTAIR has been prescribed for you, ask your doctor.

Before you use ELTAIR

When you must NOT use it

Do not use ELTAIR if you:

- are allergic to budesonide
- have an allergy to any other ingredients listed at the end of this leaflet.
- have a severe nasal infection especially candidiasis (thrush)
- are prone to nasal bleeding
- are already taking oral or inhaled steroids except on medical advice
- have recently experienced nasal ulcers, nasal surgery or trauma
- are pregnant except on medical advice
- are breast-feeding.
- have tuberculosis (TB) except on medical advice

Do not give to children under the age of 12 years except on medical advice.

- **Do not use it after the expiry date (EXP) printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

- **Do not use if the packaging is damaged or shows signs of tampering.**
- **Do not use to treat other complaints unless your doctor says it is safe to.**

Before you start to use it

Tell your doctor or pharmacist if you have any allergies to:

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

Tell your doctor or pharmacist if you are **already using other corticosteroids**. Your dose may need to be adjusted.

Tell your doctor or pharmacist if you have a **severe nasal obstruction or have nasal congestion**.

Tell your doctor or pharmacist you have active or dormant **tuberculosis (TB)**.

Tell your doctor or pharmacist about any **infection** of the respiratory tract, nasal passages or sinuses that occurred before or occurs during your treatment with ELTAIR.

Tell your doctor or pharmacist if you have/or have recently had any **nasal injuries, nasal surgery and nasal ulcers**. Corticosteroids can slow down wound healing.

Tell your doctor if you are **pregnant/intend to become pregnant** or are **breast-feeding**.

Corticosteroids are generally **not recommended** for use during pregnancy as there is inadequate information on

the effects of budesonide on the developing child. Your doctor will weigh the risks and benefits of taking this medicine while you are pregnant. Breastfeeding is NOT recommended while taking ELTAIR.

If symptoms persist, see your doctor.

It may be necessary to use **other medicines** to complement your treatment, for example to counteract potential eye symptoms caused by the allergy.

ELTAIR is **not recommended in children under the age of 12 years** except on medical advice. Studies have shown that intra-nasal corticosteroids may affect the growth rate of children under this age.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking ELTAIR.

ELTAIR is unlikely to produce an affect on the ability to **drive or use machinery**, however, care should be taken until you know how this medicine affects you.

There is no evidence this medicine is addictive.

Taking other medicines

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

The way your body processes budesonide may be interfered with by the actions of other medicines such as **ketoconazole and itraconazole**. This

may increase the risk of Cushing's syndrome, a condition affecting your adrenal glands.

Your doctor and pharmacist may have more medicines to be careful with or avoid.

How to take it

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions ask your pharmacist or doctor.

How much to use and when use it

The usual dose for adults and children (+12 years) suffering from an allergy is:

INITIALLY

- **Total daily dose is 400 µg (Maximum dose)**

- 2 X 50 µg in each nostril in the morning and in the evening

For patients who have responded well to initial dosing or those with mild symptoms use as follows:

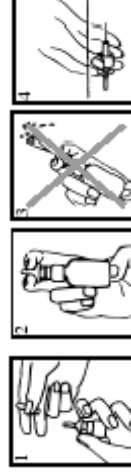
- **Total daily dose is 200 µg (Maintenance dose)**

- 1 X 50 µg in each nostril in the morning and in the evening

Do not exceed the **maximum** stated dose.

How to use it – Preparation for Use

Shake the bottle well prior to use



1. Remove the protective cap from the pump whilst gently holding the flanges (as shown).
2. Hold the atomiser upright and away from you and prime (load) the pump by **rapidly and firmly** pressing the bottle upwards (5 to 10 times) until a fine mist is produced. The atomiser is now ready for use and will not require re-priming unless used infrequently or disassembled. If the bottle does not prime easily, shake the bottle vigorously and try again.
3. If the solution is delivered in a stream of liquid, it may fail to provide benefit and may cause some discomfort. A fine mist can only be produced by a rapid and firm pumping action.
4. If the atomiser fails to work it may have become blocked. Remove the pump from the bottle and soak it in warm water for 15 minutes.

Never pierce the nozzle with a sharp object, this will render the pump useless.

How to use ELTAIR



- A. Gently blow the nose to clear the nostrils prior to administration of ELTAIR.
- B. Remove the plastic cap. Hold the atomiser as shown. Tilt your head forward slightly, close one nostril with a finger and gently insert the tip of the atomiser into the other nostril.
- C. Point the atomiser toward the back of the nostril and press the bottom of the bottle firmly and sharply to produce a fine mist.
- D. Remove the atomiser and tilt your head backwards, allowing the medication to spread

over the back of the nose. Repeat the procedure in the other nostril.

E. Replace the plastic cap after use

If you are using more than one spray in each nostril, for subsequent sprays the atomiser should be pointed in a different direction, in order for the mist to cover a wider area of the nasal passages. In case you experience some discomfort during the first application, allow an interval between sprays of two or three minutes.

In all cases, discard the bottle and the contents 3 months after opening.

How long to use it

The full effect of ELTAIR is not immediate. In the case of seasonal and non-seasonal allergies, most people will experience **an improvement in symptoms after 3-4 days**. See your doctor or pharmacist **if symptoms are not relieved after 7 days of treatment. Do not use for longer than six months without medical advice.**

If you suffer from hayfever, treatment should ideally start before the hay fever season begins to prevent symptoms from starting. If symptoms persist, see your doctor.

If you forget to use it

If you miss a dose of ELTAIR, take your dose as soon as you remember. Resume your treatment at the next usual time. Do not use twice as much to make up for any missed dose. This may increase your chance of experiencing unwanted side effects. ELTAIR is most effective when used regularly.

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

While you are using it

Tell your doctor if you get an infection or injury

Do not give this medicine to anyone else even if they have the same or a similar condition to you.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ELTAIR.

If you are about to be started on a new medicine tell your doctor, dentist and pharmacist that you are using ELTAIR.

Remember to keep all of your doctor's **appointments** during continuous, long-term treatment so that your nasal lining can be inspected.

If you become pregnant, tell your doctor or pharmacist.

Side effects

All medicines have side effects. Sometimes they are serious, most of the time they are not.

The following is a list of possible side effects.

Do not be alarmed by this list.

You may not experience any of them.

Tell your doctor if you notice any of the following symptoms and they worry you:

- Nasal irritation
- Nose bleeding
- Dry nose or mouth
- Sneezing after spraying
- Nasal crust

- Headache
- Bad taste
- Strong smell of spray
- Itching of throat and larynx
- Sore throat
- Dry mouth
- Earache
- Cough
- Loss of appetite
- Nausea
- Stomach disorder
- Skin itching
- Tremor
- Tiredness
- Ear itching
- Joint aches

Tell your doctor immediately, or go to the nearest Accident and Emergency Department at your nearest hospital if you notice any of the following:

- Pus or a coloured discharge from the nose
- Fever, nasal or facial pain or swelling
- Severe nose bleeding
- Acute eye pain or visual disturbance

Tell your doctor or pharmacist if you notice anything else that is making you unwell.

Further Information

Prolonged or excessive use of ELTAIR may result in adrenal suppression and Cushing's syndrome. Adrenal suppression is characterised by feeling weak, tiredness and possibly weight loss. Cushing's syndrome is characterised by a rapid increase in fatty tissue around the face and neck.

See your doctor if you experience any of the above side effects. These side effects are rare.

In case of overdose

Contact your doctor or pharmacist or the Poisons Information Centre (telephone 0800 POISON and 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have used too much ELTAIR. Do this even if there are no signs of discomfort or poisoning.

Storage conditions

- Store ELTAIR below 25 °C.
- Do not leave it in the car or on a windowsill.
- Keep all medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or if it has passed its expiry date, ask your pharmacist what to do with any remaining nasal spray.

Product description

What it looks like

ELTAIR appears as a uniform, white, liquid suspension and comes in a 12 mL amber glass bottle fitted with a metered dose pump. 200 doses are available in the 12 mL pack size.

Ingredients

Active: Budesonide

Other ingredients: Purified water, dispersible cellulose, hydroxypropylmethyl cellulose, Sodium lauril sulphate, Polyethylene glycol 400, Butylated

hydroxy Anisole, Sodium citrate, Citric acid monohydrate, Potassium sorbate and Disodium edetate.

Supplier

Douglas Pharmaceuticals Ltd
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