

ELCOMED *nasal spray*



Composition:

Each actuation delivers 50 mcg of mometasone furoate monohydrate. Elcomed *nasal spray* provides 120 actuations.

Description & properties:

- Mometasone furoate monohydrate, the active component of Elcomed *nasal spray* is an anti-inflammatory corticosteroid.
- Elcomed *nasal spray* is a metered-dose, manual pump spray unit containing an aqueous suspension of mometasone furoate monohydrate equivalent to 0.05% w/w mometasone furoate calculated on the anhydrous basis.
- After initial priming (10 actuations), each actuation of the pump delivers a metered spray containing 100mg of suspension containing mometasone furoate monohydrate equivalent to 50µg of mometasone furoate calculated on the anhydrous basis.

Mechanism of Action:

Corticosteroids such as mometasone primarily reduce or prevent inflammation of the lining of the airways, reduce the allergic response to inhaled allergens, and inhibit the secretion of mucus within the airways.

Pharmacokinetics:

- Mometasone furoate monohydrate administered as Elcomed *nasal spray* is virtually undetectable in plasma despite the use of a sensitive assay with a lower quantitation limit (LOQ) of 50 pcg/ml.
- Studies have shown that any portion of a mometasone furoate dose which is swallowed and absorbed undergoes extensive metabolism to multiple metabolites.
- Following intravenous administration, the effective plasma elimination half-life of mometasone furoate is 5.8 hours.
- Any absorbed drug is excreted as metabolites mostly via the bile, and to a limited extent, into the urine.

Indications:

- Elcomed *nasal spray* is indicated for treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 3 years of age and older.
- It also indicated in prophylaxis of these symptoms in adults and children 12 years of age and older.

Contraindications:

- Hypersensitivity to any of the ingredients of this preparation.
- Nasal corticosteroids should be used with caution, if at all, in patients with tuberculous infection of respiratory tract, or in untreated fungal, bacterial, systemic viral infections, or ocular herpes simplex.

Side effects:

Side effects that may occur while using this medication include: headache, nosebleed, pink color to the mucus, sore throat, burning or irritation inside the nose and menstrual irregularities.

Precautions:

- The replacement of systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency and in addition, some patients may experience symptoms of withdrawal, such as joint and/or muscular pain, lassitude, and depression.
- Too rapid decrease in systemic corticosteroid dosing may cause a severe exacerbation of these symptoms.
- Very rare cases of menstrual irregularities, acneiform lesions, and cushingoid features. If such changes occur, nasal corticosteroids should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.
- Persons who are on drugs, which suppress the immune system, are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure.
- In clinical studies with Elcomed *nasal spray*, the development of localized infections of the nose and pharynx with candida albicans has occurred only rarely. When such an infection develops, the use of Elcomed *nasal spray* should be discontinued and appropriate local or systemic therapy instituted, if needed.
- Rarely, immediate hypersensitivity reactions may occur after the intranasal administration of Elcomed *nasal spray*. Extreme rare instances of wheezing have been reported.
- As with any long-term topical treatment of the nasal cavity, patients using Elcomed *nasal spray* over several months or longer should be examined periodically for possible changes in the nasal mucosa.
- Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septum ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred.
- Very rarely, nasal and inhaled corticosteroids have been associated with the development of glaucoma and/or cataracts. Therefore, close follow-up is warranted in patients with a change in vision and with a history of glaucoma and/or cataracts.

Pregnancy (category C):

- Elcomed *nasal spray* should be used during pregnancy only if the potential benefits justify the potential risk to the fetus and the dose should be reduced in this case because of normal increase in cortisone level during pregnancy.

Lactation:

Caution should be used when Elcomed *nasal spray* is administered to nursing women.

Drug Interactions:

Systemic corticosteroids, other inhaled corticosteroids or any drugs that suppress the immune system should be avoided during treatment with Elcomed *nasal spray*.

Dosage & Administration:

Adults and children 12 years of age and older:

- The usual recommended dose for prophylaxis and treatment of the nasal symptoms of seasonal rhinitis and of perennial allergic rhinitis is two sprays (50µg of mometasone furoate in each spray) in each nostril once daily (total daily dose of 200µg).

Children 3 – 11 years: one spray in each nostril once daily.

- In patients with known seasonal allergen that precipitates nasal symptoms of seasonal allergic rhinitis, prophylaxis with Elcomed *nasal spray* (200 µg/day) is recommended 2 to 4 weeks prior to the anticipated start of the pollen season.
- Improvement in nasal symptoms generally occurs within 2 days after the first dose. And Maximum benefit is usually achieved within 1 to 2 weeks.
- Patients should use Elcomed *nasal spray* daily at a regular intervals.
- Prior to initial use of Elcomed *nasal spray*, the pump must be primed by actuating ten times or until a fine sprays appear. The pump may be stored unused for up to one week without re-priming. If unused for more than one week, re-prime by actuation two times, or until a fine sprays appear.

Overdosage:

Because of low systemic bioavailability, and an absence of acute drug-related systemic findings in clinical studies, overdose is unlikely to require any therapy other than observation.

Storage:

- Keep in temperature between (20-25)°C.
- Protect from light.
- Do not put in refrigerator.

Presentation:

Plastic bottle with a nasal spray contains 8 g of Elcomed *nasal spray* /catron box.

*** THIS IS A MEDICAMENT ***

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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