

METASONE®
50 mcg/actuation, aqueous nasal spray

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about METASONE

Each actuation of METASONE nasal spray delivers mometasone furoate monohydrate equivalent to 50 mcg mometasone furoate.

Other ingredients are benzalkonium chloride, polysorbate, disodium EDTA, hydrochloric acid, purified water.

METASONE is for intranasal use.

METASONE is a metered-dose pump spray formulation unit containing a microcrystalline suspension of mometasone furoate in an aqueous medium.

Mometasone furoate is a potent anti-inflammatory corticosteroid with strong topical and weak systemic activity. When administered intranasally in therapeutic doses, it has a direct anti-inflammatory action on the nasal mucosa.

METASONE nasal spray is indicated for:

-Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

-Prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years and older.

-Relief of nasal congestion associated with seasonal allergic rhinitis, in adults and pediatric patients 2 years of age and older.

-Treatment of nasal polyps in patients 18 years of age and older.

-As adjunctive treatment to antibiotics for acute episodes of sinusitis in patients 12 years of age and older.

The way to use METASONE

Use as directed by your physician. You should not exceed the prescribed dosage. Do not stop treatment abruptly without consulting your doctor. Shake bottle well before each use.

The first time you use the nasal spray, hold the bottle upright and fill the pump by pressing the nozzle 6 or 7 times until a fine spray is produced. After initial priming, METASONE delivers about 50 mcg per metered spray and about 120 metered doses. If the spray pump containing the aqueous suspension is not used for more than 2 weeks, it may need to be partially primed by actuating the pump 1 time.

Prior to administration of the nasal suspension using the spray pump, you should blow the nose to clear nasal passages. Tilt the head slightly forward and insert the spray tip into one nostril, pointing the tip toward the back of the nose. The drug suspension should be sprayed into one nostril while holding the other nostril closed and concurrently inspiring through the nose with the mouth closed. This procedure should be repeated for the other nostril. Avoid blowing the nose for 15 minutes after inhalation. To keep the spray nozzle clean, wipe it carefully with a clean tissue after use.

The usual recommended dosages are:

Indication	Dose
Seasonal and perennial allergic rhinitis for adults >12 years	2 sprays (50 mcg/spray) in each nostril once daily (total dose 200 mcg/day)
Seasonal and perennial allergic rhinitis for children 2-11 years	1 spray (50 mcg/spray) in each nostril once daily (total dose 100 mcg/day)
Nasal polyps for adults >18 years	2 sprays (50 mcg/spray) in each nostril twice daily (total dose 400 mcg/day)
Adjunctive treatment of acute episodes of sinusitis for adults >12 years	2 sprays (50 mcg/spray) in each nostril twice daily (total dose 400 mcg/day)

In case of overdose

Acute overdosing is unlikely to occur with nasally administered corticosteroids in view of the total amount of active ingredient present. In the event that the entire contents of the bottle were administered all at once, via either oral or nasal application, clinically significant systemic adverse effects would most likely not result.

In case of missed dose

Administer the missed dose as soon as you remember. Do not take a double dose to make up for a forgotten dose.

Contraindications

This spray should not be used in case of hypersensitivity to any of the components.

Precautions

- This medication is intended for intranasal use only. Avoid spraying in eyes.
- This drug should be used with caution in patients with active or quiescent tuberculous infection of the respiratory tract or in patients with untreated fungal, bacterial or systemic viral infections or ocular herpes simplex.
- Patients who have experienced recent nasal septum ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred.
- Patients using this spray for several months should be examined periodically for possible changes in the nasal mucosa.
- You should use this drug at regular intervals since its effectiveness depends on its regular use. Treatment of seasonal rhinitis should, if possible, start before the exposure to allergens.
- Nasal and inhaled corticosteroids may result in the development of glaucoma and/or cataracts, therefore close monitoring is warranted in patients with a change in vision.
- Discontinue the treatment if hypersensitivity reactions occur after using this spray.
- The use of this drug may cause the development of localized infections of the nose and pharynx with *Candida albicans*; in this case treatment with this spray should be discontinued and appropriate local or systemic therapy instituted, if needed.
- Notify your doctor if you experience recurrent episodes of nose bleeds or nasal discomfort while using this medication.
- Systemic side effects may occur when using this spray at higher than recommended dosages; in this case the drug should be discontinued slowly.
- Ask your doctor before using this spray in case of pregnancy or lactation. Caution is advised if the drug is administered in nursing women. This drug should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.
- Your doctor will routinely monitor the growth of your child if he receives intranasal corticosteroids over extended periods.

Associations with other medications

Please inform your doctor if you are using any other medication. This drug should be used with caution in patients receiving other inhaled or systemic corticosteroids for any disease. Caution should be used with drugs that inhibit CYP3A4.

Adverse reactions

The most reported adverse reactions include headache, viral infection, sore throat, epistaxis, and cough. Other reported adverse reactions include: nasal burning and irritation, anaphylaxis and angioedema, disturbances in taste and smell, nasal septal perforation, thrush, slow wound healing, glaucoma, cataracts, immunosuppression, and adrenal insufficiency. Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack presentation

METASONE, aqueous nasal spray, 120 sprays

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