

METASONE® - D
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-D

Each actuation of METASONE-D nasal spray delivers mometasone furoate monohydrate equivalent to 50 mcg mometasone furoate and Oxymetazoline HCl 25 mcg.

Other ingredients are benzalkonium chloride, glycerin, monopropylene glycol, hydroxypropyl methylcellulose, dibasic sodium phosphate, citric acid, and purified water.

METASONE-D is for intranasal use.

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.

Oxymetazoline acts on alpha-adrenergic receptors in the vessels of the nasal mucosa producing vasoconstriction and decongestion.

METASONE-D nasal spray is indicated in the symptomatic treatment of seasonal allergic rhinitis, hay fever and perennial rhinitis in adults and children more than 6 years of age.

The way to use METASONE-D

Use as directed by your physician. You should not exceed the prescribed dosage. The first time you use the nasal spray, hold the bottle upright and fill the pump by pressing the nozzle 5 times until a fine spray is produced. After initial priming, METASONE-D delivers about 120 metered doses. If the spray pump containing the solution 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 solution 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 nasal solution 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 dosage is:

-Adults and children more than 12 years of age: one spray in each nostril twice daily, in the morning and evening.

-Children from 6 to 12 years of age: one spray in each nostril once daily.

This drug is indicated for the treatment of allergic rhinitis in its initial stage, with the purpose of achieving rapid symptomatic control. The duration of treatment will be decided by the doctor; the use of this drug should be reduced to the shortest possible time.

In case of overdose

If you suspect an overdose, or if the nasal spray has been ingested, inform your doctor at once and seek emergency medical attention.

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 the following conditions:

- Hypersensitivity to any of the components.
- Inflammation or lesions of the skin around the nostrils or nasal mucosa.
- Patients with narrow-angle glaucoma
- Patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks
- Prostatic enlargement

Precautions

- This medication is intended for intranasal use only. Avoid spraying in eyes.
- A careful evaluation by the doctor should be done before giving this drug to the following patients: patients with cardiovascular disease, metabolic disorders (such as hyperthyroidism, diabetes, porphyria, pheochromocytoma, chronic cold, and during an extended use of this drug with a higher dosage than recommended.
- 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.
- Patients who experienced recent nasal septum ulcers, nasal surgery, or nasal trauma should not use this drug until healing has occurred.
- Patients receiving this drug for a long period should be examined periodically for possible changes in nasal mucosa
- Discontinue the treatment if hypersensitivity reactions occur after using this spray.
- 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.
- 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.

Associations with other medications

Please inform your doctor if you are using any other medication.

This drug is contraindicated with monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks

Caution should be used in patients receiving other inhaled or systemic corticosteroids for any disease, with drugs that inhibit CYP3A4, tricyclic antidepressants, antihypertensive drugs, and anti-parkinsonian drugs.

Adverse reactions

The most reported adverse reactions include: epistaxis, nasal burning and dryness, nasal irritation and ulceration, reactive hyperemia, throat irritation, headache, pharyngitis and upper respiratory tract infection.

Other reported adverse reactions include: nausea, insomnia, nervousness, tremor, anxiety, irritability, tachycardia, palpitations, arrhythmia, increased blood pressure, hypersensitivity reactions, nasal septum perforation, disturbances of smell and taste, visual disturbances, glaucoma, increased intraocular pressure, cataracts, and trouble urinating.

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-D, nasal spray, 120 sprays

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Manufactured by Mediphar Laboratories -Lebanon