Mometaget™

(Mometasone Furoate)

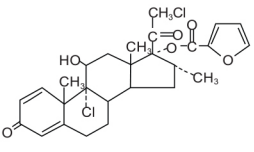
مومیٹاگیٹ

50mcg Nasal Spray

For Intranasal Use Only

DESCRIPTION

Mometaget (Mometasone Furoate) is an anti-inflammatory corticosteroid having the chemical name, 9,21-Dichloro-11ß,17-dihydroxy-16α-methylpregna-1,4-diene-3,20- dione 17-(2 Furoate). Its molecular formula is $C_{27}H_{30}Cl_2O_6$ and the structure formula is:



Mometasone Furoate

QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometaget (Mometasone Furoate) is available for administration as:

Mometaget Nasal Spray 50mcg
Each spray (100mg) contains:
Mometasone Furoate USP…50mcg

CLINICAL PHARMACOLOGY

Mechanism of Action

Mometasone Furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.
It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of Mometasone Furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone Furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients. In cell culture, Mometasone Furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNFα; it is also a potent inhibitor of leukotriene production. In addition, it is an extremely potent inhibitor of the production of the Th2 cytokines, IL-4 and IL-5, from human CD4+ T-cells.

Pharmacokinetics

Absorption

Mometasone Furoate administered as a nasal spray suspension has very low bioavailability (<1%) in plasma using a sensitive assay with a lower quantitation limit (LOQ) of 0.25pcg/mL.

Distribution

The in vitro protein binding for Mometasone Furoate was reported to be 98% to 99% in concentration range of 5 to 500ng/mL.

Metabolism

Studies have shown that any portion of a Mometasone Furoate dose which is swallowed and absorbed undergoes extensive metabolism to multiple metabolites. There are no major metabolites detectable in plasma. Upon in vitro incubation, one of the minor metabolites formed is 6ß-hydroxyMometasone Furoate. In human liver microsomes, the formation of the metabolite is regulated by cytochrome P-450 3A4 (CYP3A4).

Elimination

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.

Special Population

Patients with Hepatic Impairment

Administration of a single inhaled dose of 400mcg Mometasone Furoate to subjects with mild, moderate, and severe hepatic impairment resulted in only 1 or 2 subjects in each group having detectable peak plasma concentrations of Mometasone Furoate (ranging from 50 to 105pcg/mL). The observed peak plasma concentrations appear to increase with severity of hepatic impairment, however, the numbers of detectable levels were few.

THERAPEUTIC INDICATIONS

Mometaget (Mometasone Furoate) is indicated for the treatment of:

- Symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis and the prophylaxis of seasonal allergic rhinitis in adults, adolescents and children between the ages of 3 and 11 years.
- Nasal polyps in adult patients 18 years of age and older.
- Symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.

DOSAGE AND ADMINISTRATION

Preparation and Administration

Administer Mometaget (Mometasone Furoate) by the nasal route only.

Initial Priming

Prior to initial use of Mometaget (Mometasone Furoate), the pump must be primed by actuating ten times or until a fine spray appears. The pump may be stored unused for up to 1 week without repriming.

Repriming (as needed)

If unused for more than 1 week, reprime by actuating two times, or until a fine spray appears.

Administration to young children should be aided by an adult

Allergic Rhinitis

In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with Mometaget (Mometasone Furoate) Aqueous Nasal Spray 0.05% is recommended two to four weeks prior to the anticipated start of the pollen season.

Adults (including geriatric patients) and children 12 years of age and over

The usual recommended dose for prophylaxis and treatment is two sprays (50 micrograms/spray) in each nostril once daily (total daily dose 200 micrograms). Once symptoms are controlled, reducing the dose to one spray in each nostril (total daily dose 100 micrograms) may be effective for maintenance.

After the first dose of Mometaget (Mometasone Furoate) Aqueous Nasal Spray 0.05%, clinically significant improvement of symptoms was achieved within 12 hours in 28% of a group of patients with seasonal allergic rhinitis (median = 36 hours). However, the full benefit of treatment may not be achieved in the first 48 hours, therefore, the patient should continue regular use to achieve full therapeutic benefit.

Children between the ages of 3 and 11 years

The usual recommended dose is one spray (50 micrograms/spray) in each nostril once daily (total daily dose 100 micrograms).

Nasal Polyposis

Adults (including geriatric patients) and adolescents 18 years of age and older

The usual recommended dose for polyposis is two sprays (50 micrograms/spray) in each nostril once daily (total daily dose of 200 micrograms). If symptoms are inadequately controlled, the dose may be increased to a daily dose of two sprays in each nostril twice daily (total daily dose of 400 micrograms). Dose reduction is recommended following control of symptoms.

Acute rhinosinusitis

The usual recommended dose for acute rhinosinusitis is two sprays (50 micrograms/spray) in each nostril twice daily (total daily dose of 400 micrograms). If no improvement is seen after 15 days of twice daily administration, alternative therapies should be considered. If symptoms worsen during treatment, the patients should be advised to consult their physician.

CONTRAINDICATIONS

- Mometasone Furoate is contraindicated in patients with hypersensitivity to the active substance, or to any of the excipient of the product.
- Mometasone Furoate should not be used in the presence of untreated localized infection involving the nasal mucosa, such as herpes simplex.
- Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

ADVERSE REACTIONS

Following adverse reactions have been reported with the use of Mometasone Furoate: Epistaxis, nasal ulcerations, candida albicans infection, impaired wound healing, glaucoma, increased intraocular pressure, blurred vision and cataracts, immunosuppression and risk of infections, hypercorticism, adrenal suppression, including growth reduction, headache, viral infection, pharyngitis, cough, upper respiratory tract infection, dysmenorrhea, musculoskeletal pain, sinusitis, hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, dyspnea, nasal burning, nasal irritation, nasal ulceration, nasal septum perforation, throat irritation and disturbance of taste and smell, sneezing, growth suppression, diarrhea, nausea and abdominal pain.

"To report SUSPECTED ADVERSE REACTIONS to Getz Pharma's Pharmacovigilance Section, please contact at dsafety@getzpharma.com or +92-21-38636363"

PRECAUTIONS

Epistaxis

Epistaxis was observed more frequently in patients with allergic rhinitis and patients with chronic rhinosinusitis with nasal polyps who received Mometasone Furoate than those who received placebo.

Candida Infection

Localized infections of the nose and pharynx with Candida albicans has occurred from nasal administration of Mometasone Furoate. When such an infection develops, use of Mometasone Furoate should be discontinued and appropriate local or systemic therapy instituted, if needed.

Nasal Septum Perforation

Instances of nasal septum perforation occurred in patients following the nasal application of corticosteroids, including Mometasone Furoate. As with any long-term topical treatment of the nasal cavity, patients using Mometasone Furoate over several months or longer should be examined periodically for possible changes in the nasal mucosa.

Impaired Wound Healing

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.

Glaucoma and Cataracts

Glaucoma and cataracts may be reported with systemic and topical (including nasal, inhaled and ophthalmic) corticosteroid use. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use Mometasone Furoate long term.

Hypersensitivity Reactions

Hypersensitivity reactions including instances of wheezing may occur after the nasal administration of Mometasone Furoate. Discontinue Mometasone Furoate if such reactions occur.

Immunosuppression and Risk of Infections

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 nonimmune children or adults on corticosteroids. If patients are exposed, medical advice should be sought without delay.
Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculous infection of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections, or ocular herpes simplex because of the potential for worsening of these infections.
Patients should be cautioned not to spray Mometasone Furoate nasal spray into the eyes or directly onto the nasal septum.

Hypercorticism and Adrenal Suppression

Hypercorticism and adrenal suppression may occur when nasal corticosteroids, including Mometasone Furoate, are used at higher than recommended dosages or in patients at risk for such effects. If such changes occur, the dosage of Mometasone Furoate should be discontinued slowly, consistent with accepted procedures for discontinuing oral corticosteroid therapy.

Effect on Growth

Corticosteroids, including Mometasone Furoate, may cause a reduction in growth velocity when administered to pediatric patients. Routinely, monitor the growth of pediatric patients receiving Mometasone Furoate. To minimize the systemic effects of nasal corticosteroids, including Mometasone Furoate, titrate each patient's dose to the lowest dosage that effectively controls his/her symptoms.

Excipient

Mometasone Furoate nasal spray contains benzalkonium chloride. Long term use may cause oedema of the nasal mucosa.

Pregnancy

There are no or limited amount of data from the use of Mometasone Furoate in pregnant women. As with other nasal corticosteroid preparations, Mometasone Furoate Nasal Spray should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Nursing Mothers

It is unknown whether Mometasone Furoate is excreted in human milk. As with other nasal corticosteroid preparations, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Mometasone Furoate Nasal Spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

DRUG INTERACTION

Concomitant administration of CYP3A4 inhibitors may inhibit the metabolism of, and increase the systemic exposure to, Mometasone Furoate and potentially increase the risk for systemic corticosteroid side effects. Caution should be exercised when considering the coadministration of Mometasone Furoate with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, cobicistat-containing products, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin). Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side effects.

OVERDOSAGE

Symptoms

Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

Management

Because the systemic bioavailability of Mometasone Furoate Nasal Spray is <1%, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

STORAGE

Do not store above 30°C.
Protect from light.
Do not freeze.
Shake well before each use.

Do not use longer than 2 months after first use.

HOW SUPPLIED

Mometaget (Mometasone Furoate) Nasal Spray 50mcg is supplied in a bottle fitted with a metered-dose, manual spray pump and a cap in a pack size of 120 sprays.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

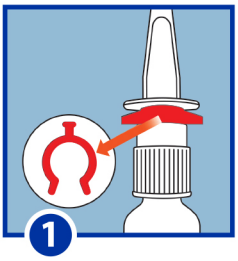
Please read the contents carefully before use.
This package insert is continually updated from time to time.

Manufactured by:
Saffron Pharmaceuticals (Pvt.) Ltd.
19km, Sheikhupura Road, Faisalabad, Pakistan

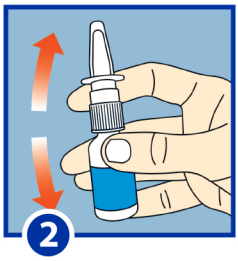
Manufactured for:

Getz pharma (PVT) LIMITED
www.getzpharma.com
29-30/27, K.I.A., Karachi, Pakistan

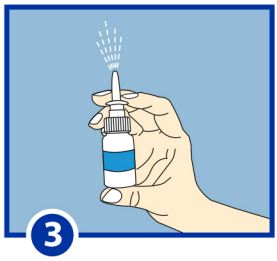
Mometaget™ | INSTRUCTIONS FOR USE



Remove the red ring.

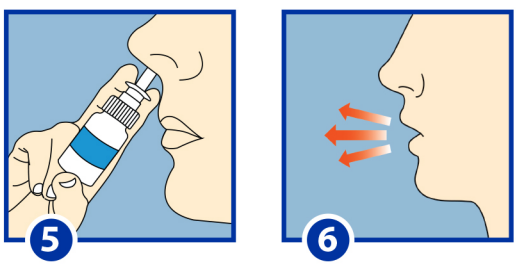


Shake the bottle well and remove the transparent protective cap.



When the spray is used for the first time, prime the pump by pressing downward on the right and left sides of the white nasal applicator using your index and middle fingers while holding the base of the bottle with your thumb. DO NOT pierce the nasal applicator. Press down and release the pump few times until a fine spray appears.

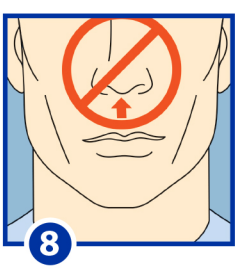
Gently blow your nose to clear the nostrils. Close one nostril. Tilt your head forward slightly, keep the bottle upright. Carefully insert the nasal applicator into the other nostril. Do not spray directly onto Nasal Septum.



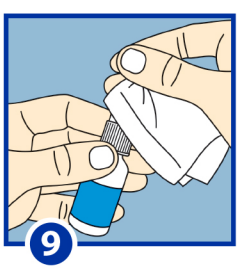
For each spray, hold the spray bottle upright and press firmly downward one time on the shoulder of the nasal applicator using your index and middle fingers while supporting the base of the bottle with your thumb. Breathe gently inward through the nostril.

Then breathe out through the mouth.

Repeat in the other nostril.



Do not tilt your head back after dosing. This will stop the medicine going into your throat and causing an unpleasant taste.



After each use, wipe the nasal applicator with a clean tissue or cloth and replace the transparent protective cap.

APPLICATOR CLEANING INSTRUCTIONS

1. To clean the nasal applicator, remove the transparent protective cap.
2. Pull gently upward on the white nasal applicator to remove.
3. Soak the nasal applicator in cold tap water and/or rinse both ends of the nasal applicator under cold tap water and dry. Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.
4. Rinse the plastic cap under cold water and dry.
5. Put the nasal applicator back together making sure the pump stem is reinserted into the applicator's center hole.
6. Reprime the pump by pressing downward on the shoulders of the white nasal applicator using your index and middle fingers while holding the base of the bottle with your thumb. Press down and release the pump two times or until a fine spray appears. DO NOT spray into eyes. The pump is now ready to use. The pump may be stored unused for up to one week without repriming. If unused for more than one week, reprime by spraying two times or until a fine spray appears.
7. Replace the transparent protective cap.

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