Tabunex®

Mometasone Furoate
Aqueous Nasal spray

Composition:
Each metered-dose pump actuation of **Tabunex** aqueous nasal spray delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 microgram mometasone furoate.
Excipients: Microcrystalline cellulose and carboxymethyl cellulose sodium, glycerin, citric acid, sodium citrate, polysorbate, benzalkonium chloride, phenylethyl alcohol.

Properties:
Tabunex aqueous nasal spray is a metered-dose, manual pump spray unit containing a suspension of mometasone furoate.
Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties that are not systemically active.

Indications:
Tabunex aqueous nasal spray is indicated for use in adults, adolescents and children between the ages of 2 and 11 years to treat the symptoms of seasonal or perennial rhinitis.
In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with **Tabunex** aqueous nasal spray is recommended two to four weeks prior to the anticipated start of the pollen season.
Tabunex aqueous nasal spray is also indicated for use in adults and adolescents 12 years of age and older as adjunctive treatment to antibiotics for acute episodes of sinusitis.

Contraindications:
Tabunex aqueous nasal spray is contraindicated in patients with known hypersensitivity to any of its components.

Precautions:
Tabunex aqueous nasal spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.
As with other nasal corticosteroid preparations, **Tabunex** aqueous nasal spray should be used in pregnant woman, nursing mothers or women of childbearing age only if the potential benefit justifies the potential risk to the mother, fetus or infant. Infant born to mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Interactions with other drugs:
Tabunex aqueous nasal spray has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite.
Mometasone furoate plasma concentrations were not detectable. The combination therapy was well tolerated.

Warnings:
Tabunex aqueous nasal spray should not be used in the presence of untreated localized infection involving the nasal mucosa.
As with any long-term treatment, patients using **Tabunex** aqueous nasal spray over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localized fungal infection of the nose or pharynx develops, discontinuance of **Tabunex** aqueous nasal spray or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing **Tabunex** aqueous nasal spray.

Dosage and Administration:
Seasonal allergic or perennial rhinitis: After initial priming of **Tabunex** aqueous nasal pump (usually 6 or 7 actuations, until a uniform spray is observed), each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed before next use.
Shake container well before each use.
Adults (including geriatric patients) and adolescent: The usual recommended dose for prophylaxis and treatment is two sprays (50 micrograms/spray) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one spray in each nostril (total dose 100 micrograms) may be effective for maintenance.
If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of four sprays in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.
Clinically significant onset of action occurs as early as 12 hours after the first dose.
Children between the ages of 2 and 11 years: The usual recommended dose is one spray (50 micrograms/spray) in each nostril once daily (total dose 100 micrograms).
Administration to young children should be aided by an adult.
Adjunctive treatment of acute episodes of sinusitis: Adults (including geriatric patients) and adolescents 12 years of age and older: The usual recommended dose is two sprays (50 micrograms/spray) in each nostril twice daily (total dose 400 micrograms).
If symptoms are inadequately controlled, the dose may be increased to four sprays (50 micrograms/spray) in each nostril twice daily (total dose 800 micrograms).

Overdosage:
Because of the negligible (< 0.1%) systemic bioavailability of **Tabunex**, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

Side Effects:
> 10%: Headache, pharyngitis, cough, epistaxis, viral infection.
1% to 10%: Chest pain, dysmenorrheal, vomiting, diarrhea, dyspepsia, nausea, musculoskeletal pain, arthralgia, myalgia, conjunctivitis, earache, otitis media, upper respiratory tract infection, sinusitis, asthma, bronchitis, nasal irritation, rhinitis, wheezing, flu-like symptoms.
Consult your pharmacist or physician if any side effect is observed.

Pharmaceutical Precautions:
Keep at room temperature (15-30°C).
Do not freeze.
Shake well before use.
Do not use beyond the expiry date or if the product shows any signs of deterioration.

Presentation:
Each pack contains at least 120 metered sprays.

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the 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.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.

Dec.2009
44219/R3

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