

RINEX®
55 mcg/actuation, 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 RINEX

Each actuation of RINEX nasal spray suspension delivers 55 mcg triamcinolone acetonide.

Other ingredients: sodium carboxymethyl cellulose, sodium EDTA, water.

RINEX is for intranasal use.

RINEX is a metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium.

Triamcinolone acetonide 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.

RINEX nasal spray is indicated for the prophylaxis and treatment of seasonal and perennial allergic rhinitis symptoms in adults and children 2 years of age and older.

In patients with seasonal or perennial allergic rhinitis, intranasal administration of RINEX generally provides symptomatic relief of rhinorrhea, nasal congestion, sneezing, and itching. In addition to relief of nasal symptoms, improvement of ophthalmic signs and symptoms (e.g., itching, lacrimation) may occur in some patients.

The way to use RINEX

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 5 times until a fine spray is produced. After initial priming (5 actuations), RINEX delivers about 55 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:

Age	Dose
Adults and children 12 years of age and older	2 sprays (110 mcg) in each nostril once daily (220 mcg/day) Maximum dose is 220 mcg/day (two sprays per nostril once daily).
Children 6 to 12 years of age	1 spray (55 mcg) in each nostril once daily (110 mcg/day) Maximum dose is 220 mcg/day (two sprays per nostril once daily).
Children 2 to 5 years of age	1 spray (55 mcg) in each nostril once daily (110 mcg/day) Maximum dose is 110 mcg/day (1 spray per nostril once daily).

In adults and children above 6 years of age, when the maximum benefit has been achieved and symptoms have been controlled, reducing the dose to 110 mcg/day (1 spray in each nostril once a day) has been shown to be effective in maintaining control of the allergic rhinitis symptoms in patients who were initially controlled at 220 mcg/day.

The bottle should be discarded after 120 actuations even though the bottle is not completely empty since the amount of triamcinolone acetonide delivered thereafter per actuation may be substantially less than 55 mcg of drug.

An improvement in some patient symptoms may be seen within the first day of treatment, and generally, it takes one week of treatment to reach maximum benefit.

When this medicine is used in children under the age of 12 years, it is recommended that any period of continuous treatment should not exceed 3 months.

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.

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.
- Nasal corticosteroids should be used with caution until healing occurs in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma.
- 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.
- 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 clearly needed.
- Notify your doctor if symptoms worsen or fail to improve within 3 weeks or if you experience recurrent episodes of nose bleeds or nasal discomfort while using this medication.
- Your doctor will routinely monitor the growth of your child if he receives intranasal corticosteroids over extended periods.

Association with other medications

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

This drug should be used with caution in patients receiving other inhaled or systemic corticosteroids for any disease.

Adverse reactions

This spray is usually well tolerated when used as directed. The most reported adverse reactions include pharyngitis, nose bleeds, blocked nose, nasal irritation, and headache.

Localized candidal infections of the nose and/or pharynx, and allergic reactions have occurred rarely during therapy.

Inform your doctor if any side effect 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. Discard 2 months after opening the nasal spray.

Pack presentation

RINEX nasal spray suspension, triamcinolone acetonide 55 mcg/actuation, 120 sprays

Revision date: 05/2011

RINY0055/002