

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

**Adverse events should also be reported to
McNeil Products Limited on 01344 864 042**

RHINOCORT® AQUA 64 micrograms (budesonide) Prescribing Information

Presentation:

Nasal spray, suspension. Each actuation contains 64micrograms budesonide

Uses:

Seasonal and perennial allergic rhinitis and vasomotor rhinitis. Treatment of nasal polyps.

Dosage (adults):

Rhinitis: Once daily dosing: 128 micrograms into each nostril in the morning. Twice daily dosing: 64 micrograms into each nostril morning and evening. If good effect is achieved, one application of 64 micrograms into each nostril each morning.

Treatment of seasonal rhinitis should, if possible, start before exposure to the allergens. Treatment can be continued for up to 3 months.

Nasal polyps: 64mcg into each nostril morning and evening.

Full effect not achieved until after a few days treatment. Remind patients of importance of using regularly. The dose should be titrated to the lowest dose at which effective control of symptoms is achieved.

Paediatric population: insufficient data to recommend use in children and adolescents under 18 years of age.

Contraindications

Hypersensitivity to active ingredient or to any of the excipients.

Warnings and precautions:

If symptoms are not controlled or persist for longer than 2 weeks of treatment, medical advice must be sought. Patients should consult a physician before use if: they are using a corticosteroid for other conditions, they currently have or have been exposed to tuberculosis, chicken pox or measles, they have severe or frequent nose bleeds or have had nose ulcers, nose surgery or injury, they have ever been diagnosed with glaucoma or cataracts, they have an eye infection or diabetes. Special care required in the treatment of patients transferred from oral corticosteroids to this medicine, where disturbances of hypothalamic-pituitary-adrenal (HPA) axis could be expected and in patients with fungal and viral infections of the airways. Concomitant treatment of seasonal rhinitis may sometimes be necessary to treat eye symptoms caused by the allergy. In continuous long-term treatment, the nasal mucosa should be inspected regularly. Reduced liver function affects the elimination of corticosteroids, may lead to higher systemic exposure and possible systemic side effects. Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Treatment with higher than recommended doses may cause clinically significant adrenal suppression. CYP3A inhibitors may increase systemic exposure to budesonide, concomitant treatment with Rhinocort should be avoided. If co-administered with antifungals (such as itraconazole and ketoconazole), the period between treatments should be as long as possible and consider reduction in Rhinocort dose. Raised plasma concentrations and enhanced effects of corticosteroids have been observed in women treated with oestrogens and contraceptive steroids. No effect observed during concomitant intake of low dose oral

contraceptives. As adrenal function may be suppressed this may lead to false results in ACTH stimulation test for diagnosing pituitary insufficiency.

Pregnancy and lactation:

Avoid during pregnancy unless benefit outweighs risk. No effects on breast fed child are expected at therapeutic doses.

Side effects: *Consult SmPC for full list of side effects*

Common: Haemorrhagic secretion, epistaxis, nasal discomfort (sneezing, stinging and dryness).

Uncommon: Hypersensitivity (immediate and delayed) reactions including erythema, urticaria, rash, dermatitis angioedema and pruritus. Muscle spasms.

Rare: Anaphylactic reaction, signs and symptoms of systemic corticosteroid effects, including adrenal suppression and growth retardation, nasal septum perforation, nasal ulcer and dysphonia. Blurred vision. Contusion.

Very rare: Mucosal ulceration.

Not known: Raised intraocular pressure or glaucoma and cataract.

In rare cases, signs or symptoms of glucocorticosteroid-side effects such as Cushing's syndrome, Cushingoid features, psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children) may occur.

Acute overdose even in excessive doses, is not expected to be a clinical problem.

NHS cost: 120 actuations: £3.96

Legal category: POM

PL holder: McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG

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