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.

BENACORT 64 micrograms Nasal Spray (budesonide) Product Information

Presentation:

Nasal spray, suspension. Each actuation contains 64mcg budesonide

Uses:

Prevention and treatment of seasonal allergic rhinitis (hay fever).

Dosage *(adults)**:***

Once daily dosing**:** 128mcg into each nostril in the morning. Twice daily dosing: 64mcg into each nostril morning and evening. If good effect is achieved, 64 micrograms into each nostril each morning. Full effect not achieved until after a few days treatment. Treatment of seasonal rhinitis should start, if possible, before exposure to the allergens. If symptoms are not controlled, or persist for longer than 2 weeks of treatment, medical advice must be sought. Benacort should not be used continuously for longer than 3 months.

Paediatric population*:* not be used 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 nosebleed 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 needed: when treating patients transferred from oral steroids, where disturbances of hypothalamic-pituitary-adrenal (HPA) axis could be expected; in patients with fungal and viral infections of the airways. 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. CYP3A inhibitors may increase systemic exposure to budesonide. 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. Contains Potassium sorbate (E202) which may cause local skin reactions, (e.g. contact dermatitis).

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 and epistaxis. Nasal Irritation (sneezing, stinging and dryness).

Uncommon: Immediate and delayed hypersensitivity 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: Ulceration of mucous membrane.

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.

RRP (excl. VAT): 120 actuations: £8.74

Legal category: P

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

PL number: 15513/0404

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