

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® Hayfever Relief for Adults 64 micrograms (budesonide) Product Information

Presentation:

Nasal spray, suspension. Each actuation contains 64mcg budesonide

Uses:

Treatment of seasonal allergic rhinitis (hay fever).

Dosage (adults):

Initially: Two sprays (128mcg) into each nostril in the morning. Once symptoms are under control, use a maintenance dose of one spray (64 micrograms) into each nostril each morning. No more than four sprays in one day. Full effect not achieved until after a few days treatment. If symptoms are not controlled, or persist for longer than 7 days of treatment, medical advice must be sought. Benacort should not be used continuously for longer than 1 month without medical advice.

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, and patients taking HIV medications. See the SmPC for further details.

Warnings and precautions:

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 fungal or viral infections of the airways, 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. Patients should consult a pharmacist or doctor if they develop signs or symptoms of an infection, such as persistent fever, while taking this medicine. 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 used for prolonged periods. Co-treatment with CYP3A inhibitors including cobicistat-containing products is expected to increase the risk of systemic side effects. In cases of clinically significant adrenal suppression, additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Raised plasma concentrations and enhanced effects of corticosteroids have been observed in women treated with oestrogens and contraceptive steroids, but no effect has been observed during concomitant intake of low dose combination oral contraceptives. As adrenal function may be suppressed this may lead to false results in ACTH stimulation test for diagnosing pituitary insufficiency. See the SmPC (summary of product characteristics) for full details. 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. This medicine should not be used during pregnancy or breast-feeding without first consulting a doctor or pharmacist.

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

Common: Haemorrhagic secretion, epistaxis. Nasal discomfort (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, 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): 60 actuations: £6.99.

Legal category: GSL

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

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