Product Information for Benacort Hayfever Relief for Adults 64 micrograms, nasal spray, Benacort 64 micrograms Nasal Spray, Benadryl Allergy Relief, Benadryl Allergy Relief Plus Decongestant Capsules, Benadryl One A Day Relief/ Benadryl Allergy One a Day 10mg Tablets

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

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

Benacort® Hayfever Relief for Adults 64 micrograms Nasal Spray (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

PL number: 15513/0409

Date of preparation: 28 March 2023.

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: £9.16
Legal category: P
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK
PL number: 15513/0404
Date of preparation: 28 March 2023

Benadryl Allergy Relief (Acrivastine 8mg) Product Information

Presentation:
Acrivastine 8 mg capsules.

Uses:
Symptomatic relief of allergic rhinitis. Also chronic idiopathic urticaria.

Dosage:

Adults and children aged 12 - 65 years: One capsule up to 3 times a day.

Contraindications:
Hypersensitivity to acrivastine or triprolidine or any excipients listed in section 6.1 of the SPC. Severe renal impairment. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Precautions:
Concomitant administration of acrivastine with CNS depressants may produce additional impairment in mental alertness in some individuals. Patients with renal impairment should consult with a physician before use.
This product may cause drowsiness. Acrivastine may cause dizziness and somnolence- caution when engaging in activities which require mental alertness until familiar with response to drug. Caution when taking with ketoconazole, erythromycin or grapefruit juice.

Pregnancy and Lactation:
Not recommended

Side effects:
Very common: somnolence. *Common*: dry mouth, dizziness
Unknown: hypersensitivity (including dyspnoea and face swelling), rash.
RRP (ex VAT): 12s £5.24, 24s £8.62, 48s: £15.41
Legal category: 12s GSL, 24s GSL, 48s P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
PL Number: 12s & 24s 15513/0128, 48s 15513/0035
Date of prep: 07/12/2020

Benadryl Allergy Relief Plus Decongestant Capsules, Product Information:

Presentation: Acrivastine 8mg and pseudoephedrine 60mg capsules.
Uses: Symptomatic relief of allergic rhinitis.
Dosage: Adults and children 12 - 65 years: One capsule as necessary, up to three times a day.
Contraindications: Hypersensitivity to the active substances, antihistamine triprolidine or to any of the excipients. Cardiovascular disease including hypertension, concomitant use of beta blockers or other sympathomimetic decongestants, diabetes mellitus, phaeochromocytoma, closed angle glaucoma, hyperthyroidism, significant or severe renal impairment. in patients who are taking or have taken MAOI's in the preceding 14 days. Contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Precautions: Severe hepatic impairment, moderate to severe renal impairment or occlusive vascular disease. Effects of alcohol or other CNS depressants may be enhanced. Patients taking sympathomimetics, antihypertensives, anticholinergic drugs such as tricyclic antidepressants, oxytocin, cardiac glycosides, ergot alkaloids, moclobemide, anaesthetic agents, ketoconazole, erythromycin or grapefruit juice. Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones, decreased kidney function should not take pseudoephedrine unless directed by a physician. If any of the

following occur, this product should be stopped: hallucinations, restlessness, sleep disturbances. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine containing products. Some cases of ischaemic colitis have been reported with pseudoephedrine. Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. Rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) have been reported with sympathomimetic drugs, including pseudoephedrine.
Pregnancy & lactation: Not recommended.
Side effects: Hypersensitivity (including dyspnoea and face swelling), cross-sensitivity with other sympathomimetics, insomnia, nervousness, anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, sleep disorder, headache, somnolence, dizziness, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, tremor, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension, dry mouth, nausea, ischaemic colitis, ischaemic optic neuropathy, vomiting, angioedema, pruritus, rash, severe skin reactions, including acute generalised exanthematous pustulosis (AGEP), dysuria, urinary retention in men in whom prostatic enlargement could have been an important predisposing factor.
RRP (ex-VAT): 12s £5.82
Legal cat: P
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
PL no: 15513/0017
Date of prep: 08 Aug 2023.

Benadryl One A Day Relief / Benadryl Allergy One A Day 10 mg Tablets, Cetirizine, Product Information

Presentation:
Cetirizine dihydrochloride 10mg film-coated tablets with breakline and Y-Y logo. Excipients with known effect: lactose monohydrate.

Uses:
Symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

Dosage:
12 years and above: 10mg once daily.

Contraindications:
Hypersensitivity to ingredients, hydroxyzine or piperazine derivatives; severe renal impairment, galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Precautions:
Renal impairment: dosage adjustment required - refer to SPC. Caution with concomitant alcohol consumption, in epilepsy and those at risk of convulsions. Caution in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia). Do not drive or operate machinery until familiar with response to drug. Severe skin reactions such as acute generalised exanthematous

pustulosis (AGEP) have been reported very rarely with cetirizine-containing products - refer to SPC.

Fertility, Pregnancy and Lactation:
Caution should be exercised when prescribing to pregnant or lactating women..

Side effects:
Common: Somnolence, fatigue, dizziness, headache, abdominal pain, dry mouth, nausea, pharyngitis, rhinitis.
Uncommon: agitation, paraesthesia, diarrhoea, pruritus, rash, asthenia, malaise.
Rare: Hypersensitivity, aggression, confusion, depression, hallucination, insomnia, convulsions, tachycardia, hepatic function abnormal, urticaria, oedema, weight increased.
Very rare: thrombocytopenia, anaphylactic shock, tics, dysgeusia, syncope, tremor, dystonia, dyskinesia, accommodation disorder, blurred vision, oculogyration, angioneurotic oedema, dysuria, enuresis, fixed drug eruption. *Not known:* increased appetite, suicidal ideation, amnesia, memory impairment, eye pain, vertigo, urinary retention, erectile dysfunction, acute generalised exanthematous pustulosis (AGEP), arthralgia, pruritus upon withdrawal, hepatitis.
RRP (ex-VAT)/NHS Cost: 7s £5.13; 14s £6.83; 30s £8.33.
Legal category: GSL.
PL Holder: McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.
PL Number(s): 15513/0118.
Date of prep: 16 Nov 2023