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

Abbreviated Prescribing Information

Please consult Summary of Product Characteristics for full prescribing information

Benadryl Allergy Relief (Acrivastine 8mg)

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.

NHS Price: 12s £3.20, 24s £5.45, 48s £9.91

Legal category: 12s GSL, 24s GSL, 48s P

PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.

PL Number: 12s & 24s 15513/0128, 48s 15513/0035

Date of prep: 31/12/2017

Benadryl Allergy Children's 1mg/mL Oral Solution (Cetirizine dihydrochloride 1mg/ml solution)

Presentation:

Clear and Colourless liquid.

Uses:

Symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

Dosage:

2-6 years: 2.5mL twice daily; 6-12 years: 5mL twice daily; 12 years and above: 10ml once daily.

Contraindications:

Hypersensitivity, severe renal impairment.

Precautions:

Renal/Hepatic impairment: dosage adjustment required - refer to SPC. Caution with concomitant alcohol consumption, in epilepsy and those at risk of convulsions, in patients with predisposing factors of urinary retention and hereditary fructose intolerance. Do not drive or operate machinery until familiar with response to drug. Wash-out period of 3 days is recommended before performing an allergy skin test.

Pregnancy and Lactation:

On health care professional advice only. Should not be used during pregnancy or breastfeeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or nursing infant.

Side effects:

Common: Somnolence, fatigue, dizziness, headache, abdominal pain, dry mouth, nausea, pharyngitis, diarrhoea, rhinitis. Rare: Hypersensitivity, aggression, confusion, depression, hallucination, insomnia, convulsions, movement disorders, tachycardia, hepatic function abnormal, urticaria, oedema, weight increased. Very rare: thrombocytopenia, anaphylactic shock, tics, dysgeusia, dystonia, dyskinesia, angioneurotic oedema, fixed drug eruption, syncope, tremor, accommodation disorder, blurred vision, oculogyration, eye swelling, cough, dysuria, enuresis, feeling abnormal. Uncommon: agitation, paraesthesia, diarrhoea, pruritus, rash, asthenia, malaise. Not known: increased appetite, suicidal ideation, amnesia, memory impairment, vertigo, urinary retention, eye pain, erectile dysfunction.

NHS Price: 100mL £3.49

Legal category: P

PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.

PL Number: PL 15513/0138

Date of prep: 18/04/2018

BENACORT 64 micrograms Nasal Spray (budesonide)**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 or 64mcg into each nostril if good effect is achieved. Twice daily dosing: 64mcg into each nostril morning and evening. 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 nose bleed 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.

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.

NHS Price: 120 actuations: £5.83

Legal category: P

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

PL number: 15513/0404

Date of Preparation: 18 July 2018

Benadryl Allergy Relief Plus Decongestant Capsules

Presentation:

Acrivastine 8mg and pseudoephedrine 60mg capsules.

Uses:

Symptomatic relief of allergic rhinitis.

Dosage:

Adults and children 12 years and over: One capsule as necessary, up to three times a day.

Contraindications:

Hypersensitivity or intolerance to any of the ingredients or triprolidine. Severe hypertension, severe heart disease or significant renal impairment; patients who have taken MAOI's in the preceding 14 days. Concomitant use with furazolidone.

Precautions:

Diabetes, hyperthyroidism, heart disease, hypertension, glaucoma or prostatic enlargement. Advise patients not to undertake tasks requiring mental alertness whilst under the influence of alcohol or other CNS depressants. Effects of alcohol or other CNS depressants may be enhanced. Patients taking sympathomimetics, antihypertensives, and tricyclic antidepressants.

Pregnancy & lactation:

Should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus.

Side effects:

Rarely drowsiness, CNS excitement; occasionally skin rash, or urinary retention in men.

NHS Price: 12s £3.79

Legal cat: P

PL holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.

PL 15513/0017

Date of prep: 15th May 2015