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 0808 238 9999.

Benadryl Allergy Relief Plus Decongestant Capsules (Acrivastine and Pseudoephedrine Hydrochloride) Product Information

Presentation:
Acrivastine 8mg and pseudoephedrine hydrochloride 60mg capsules.

Uses:
Symptomatic relief of allergic rhinitis.
Dosage:
Adults and children 12 to 65 years: one capsule as necessary, up to three times a day.
Contraindications:
This product is not for use in children under 12 years of age and in the elderly. It is also contraindicated in individuals with known hypersensitivity to acrivastine, pseudoephedrine hydrochloride, or to any of its excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product is also contraindicated in individuals with concomitant use of other sympathomimetic decongestants, beta-blockers, or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. The concomitant use of MAOIs may cause a rise in blood pressure and/or hypertensive crisis.
Precautions:
This product contains lactose monohydrate; patients with hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicine. Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment and in occlusive vascular disease. Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones, or patients with decreased kidney function should not take pseudoephedrine-containing products unless directed by a physician. This product should be discontinued if hallucinations, restlessness, or sleep disturbances occur.
Pseudoephedrine has known interactions with the following medicinal products: moclobemide, antihypertensives such as bretylium, betanidine, guanethidine, debrisoquine, methyldopa, adrenergic neurone blockers and beta blockers, cardiac glycosides, ergotamine and methysergide, appetite suppressants and amphetamine-like psychostimulants, oxytocin, tricyclic antidepressants, or halogenated anaesthetic agents. There are no data to demonstrate an interaction between acrivastine and ketoconazole, erythromycin, or grapefruit juice. However, due to known interactions

between these compounds and other non-sedating antihistamines, caution is advised. It may also enhance the sedative effects of central nervous system depressants, including alcohol, sedatives and tranquilisers.
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued, and appropriate measures taken if needed.
Some cases of ischaemic colitis have been reported with pseudoephedrine. This product should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. This product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.
Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.
This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.
Please refer to Summary of Product Characteristics for detailed information.

Pregnancy & lactation:

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or nursing infant.

Side effects:

Very Common: headache, somnolence
Common: insomnia, nervousness, dizziness, dry mouth, nausea
Not Known: hypersensitivity (including dyspnoea and facial swelling), cross-sensitivity with other sympathomimetics, anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, sleep disorder, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES), reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, tremor, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension, ischaemic colitis, 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)
Please refer to Summary of Product Characteristics for detailed information.

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
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