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.

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:**

<u>*Common:*</u> Somnolence, fatigue, dizziness, headache, abdominal pain, dry mouth, nausea, pharyngitis, rhinitis.

<u>Uncommon</u>: agitation, paraesthesia, diarrhoea, pruritus, rash, asthenia, malaise. <u>Rare:</u> Hypersensitivity, aggression, confusion, depression, hallucination, insomnia, convulsions, tachycardia, hepatic function abnormal, urticaria, oedema, weight increased.

<u>Very rare:</u> thrombocytopenia, anaphylactic shock, tics, dysgeusia, syncope, tremor, dystonia, dyskinesia, accommodation disorder, blurred vision,

oculogyration, angioneurotic oedema, dysuria, enuresis, fixed drug eruption. <u>Not known:</u> 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, REF-PI-BN-0036

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