

**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 freephone 0808 238 9999.**

## **Multi-Action ACTIFED Tablets (Triprolidine hydrochloride, Pseudoephedrine hydrochloride) Product Information:**

**Presentation:** Tablets containing triprolidine hydrochloride 2.5mg, pseudoephedrine hydrochloride 60mg.

**Uses:** Symptomatic relief of upper respiratory tract disorders including allergic rhinitis, vasomotor rhinitis, the Common Cold and Influenza.

**Dosage:** Adults and children over 12 years: One tablet every 4-6 hours up to 4 times a day. Children under 12 years: Not recommended.

**Contraindications:** Hypersensitivity to pseudoephedrine or triprolidine or to its excipients, patients who are taking or have taken monoamine oxidase inhibitors within the preceding 14 days (the concomitant use of pseudoephedrine and this type of product may cause a rise in blood pressure and/or hypertensive crisis), concomitant use of other sympathomimetic decongestants or beta-blockers, patients with cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, and severe renal impairment

**Precautions:** May cause drowsiness. This product should not be used to sedate a child. Triprolidine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives and tranquilisers. While taking Multi-Action ACTIFED Tablets, patients should be advised to avoid alcoholic beverages. Use with caution in prostatic hypertrophy, urinary retention or susceptibility to angle closure. Patients with thyroid disease who are receiving thyroid hormones are advised to consult a physician before using this product. Use with caution in occlusive vascular disease. Product should be stopped if patients experience hallucinations, restlessness, sleep disturbances. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine containing products. Cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine 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. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Patients with the

following conditions should not use Multi-Action Actifed Tablets unless directed by a physician: acute or chronic asthma, chronic bronchitis or emphysema. Caution should be exercised in the presence of hepatic or moderate to severe renal or hepatic impairment. This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Pregnancy and 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 breastfeeding infant.

There are no adequate and well-controlled studies for pseudoephedrine or triprolidine, or for the combination of pseudoephedrine and triprolidine, in pregnant women.

**Side effects:**

Very Common: Headache.

Common: Insomnia, Nervousness, Dizziness, Paradoxical stimulation, Psychomotor impairment, Somnolence, Vision blurred, Increased viscosity of bronchial secretion, Dry mouth, Gastrointestinal disorder, Nausea, Urinary Retention (in men whom prostatic enlargement could have been an important predisposing factor).

Not Known: Ischaemic optic neuropathy, Anxiety, Euphoric mood, Excitability, Hallucinations, Irritability, Paranoid delusions, Restlessness, Cerebrovascular accident, Paraesthesia, Posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), Psychomotor hyperactivity, Dysrhythmias, Myocardial infarction / myocardial ischaemia, Tachycardia, Hypertension, Dry throat, Epistaxis, Nasal dryness, Abdominal discomfort, Ischaemic colitis, Vomiting, Angioedema, Pruritus, Rash, Severe skin reactions including acute generalised exanthematous pustulosis (AGEP), Urticaria, Dysuria, Fatigue.

Rare: Blood disorder, Hypersensitivity – cross-sensitivity may occur with other sympathomimetics, Confusional state, Depression, Sleep disorder, Extraparal disorder, Seizure, Tremor, Palpitations, Hypotension, Liver disorder.

**RRP (ex-VAT):** 12s: £5.11

**Legal category:** P

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

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