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 Dry Coughs Product Information:

Presentation: Liquid containing 1.25mg triprolidine hydrochloride, 30mg pseudoephedrine hydrochloride and 10mg dextromethorphan hydrobromide in each 5 ml. Each 5ml also contains the following excipients: Sorbitol solution (E420), Sucrose, Methyl hydroxybenzoate (E218), Ponceau 4R (E124), Ethanol, Sodium Benzoate (E211), Sodium.
Uses: Symptomatic relief of upper respiratory tract disorders.
Dosage: Oral. Adults and children over 12 years: 10 ml every 4 -6 hours up to four times a day.
Contraindications: Children under the age of 12 years; hypersensitivity to ingredients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe renal impairment; and concomitant use of other sympathomimetic decongestants, beta-blockers, selective serotonin reuptake inhibitors (SSRIs) or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment.
The concomitant use of this product and MAOIs may cause a rise in blood pressure and/or hypertensive crisis. There is a risk of serotonin syndrome with dextromethorphan. Dextromethorphan should not be given to patients in, or at risk of developing respiratory failure.
Precautions: May cause drowsiness. This product should not be used to sedate a child. This product should not be taken with any other cough and cold medicines. Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions.
Avoid concomitant alcohol or other centrally acting sedatives, triprolidine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives and tranquilisers and use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. Caution in patients with difficulty in urination and/or prostatic enlargement, or patients with thyroid disease who are receiving thyroid hormones, susceptibility to angle closure glaucoma, moderate to severe renal impairment, hepatic impairment, occlusive vascular disease, and in children with atopy. Caution should also be exercised in individuals who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors. This product should be stopped if hallucinations, restlessness or sleep disturbances occur.

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 and this product should be discontinued if sudden abdominal pain, rectal bleeding or other symptoms of ischemic 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. Pseudoephedrine should be discontinued, and medical advice sought immediately, when onset of severe headache, nausea, vomiting, and visual disturbances occur.
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).
Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors. If serotonin syndrome is suspected, treatment with this medicine should be discontinued.
Caution regarding the following excipients:

- This medicine contains 208 mg of alcohol (ethanol) in each 5 ml. The amount in each 5 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 5 mg sodium benzoate (E211) in each 5 ml.
- Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).
- The colouring in this medicine (Ponceau 4R, E124) may cause allergic reactions.
- This medicine contains 2.8 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.
- This medicine contains 1 g sorbitol in each 5 ml. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

See SPC for further precautions.

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 available on the effects of administration of this product in pregnant women. Pseudoephedrine has been in widespread use for many years without any apparent ill consequence. The safety of pseudoephedrine in pregnancy has not been established. There is insufficient information available to determine whether dextromethorphan has teratogenic potential.

Side effects:
Very common: Headache
Common: Insomnia, Nervousness, Dizziness, Paradoxical stimulation, Psychomotor impairment, Somnolence, Extrapyramidal disorder, Seizure, Vision blurred, Increased viscosity of bronchial secretion, Dry mouth, Gastrointestinal disorder, Nausea, Urinary Retention
Rare: Blood disorder, Hypersensitivity – cross-sensitivity may occur with other sympathomimetics, Confusional state, Depression, Sleep Disorder, Tremor, Cerebrovascular accident, Paraesthesia, Palpitations, Hypotension, Liver disorder
Not known: Anxiety, Drug dependence, Euphoric mood, Excitability, Hallucinations, Irritability, Paranoid delusions, Restlessness, Posterior reversible encephalopathy syndrome (PRES) / Reversible cerebral vasoconstriction syndrome (RCVS), Psychomotor hyperactivity, Ischaemic optic neuropathy, Dysrhythmias, Myocardial infarction/myocardial ischaemia, Tachycardia, Hypertension, Dry Throat, Epistaxis, Nasal dryness, Respiratory depression, Abdominal pain, Diarrhoea, Ischaemic colitis, Vomiting, Angioedema, Pruritus, Rash, Severe skin reactions including acute generalised exanthematous pustulosis (AGEP), Urticaria, Dysuria, Drug withdrawal syndrome, Fatigue
RRP (ex-VAT): 100ml: £5.32
Legal category: P.
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK
PL number:15513/0010.
Date of prep: 09 May 2022