**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 (triprolidine hydrochloride, pseudoephedrine hydrochloride, dextromethorphan hydrobromide) Product Information

**Presentation**:
Liquid containing 1.25 mg triprolidine hydrochloride, 30 mg pseudoephedrine hydrochloride and 10 mg 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:**
*Adults and children over 12 years:* 10 ml every 4 to 6 hours (maximum of four times a day). Not more than 4 doses should be given in any 24 hours.

**Contraindications:**
This product should not be used in children under 12 years. This product is contraindicated in individuals with known hypersensitivity to triprolidine, pseudoephedrine, dextromethorphan, or to any of the excipients; cardiovascular disease, severe hypertension or uncontrolled hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken selective serotonin reuptake inhibitors (SSRIs) or monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis. Concomitant intake of dextromethorphan with other serotonergic agents, such as SSRIs, can induce serotonergic effects, including the development of a potentially life-threatening serotonin syndrome. Dextromethorphan should also not be given to patients in or who are at risk of developing respiratory failure. This product contains 2.8 g sucrose and 1 g sorbitol per 5 ml; therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine. It also contains Ponceau 4R (E124) red colouring and methyl hydroxybenzoate (E218), both of which may cause allergic reactions.

**Precautions:**
Multi-Action ACTIFED Dry Coughs may cause drowsiness. This product should not be used to sedate a child. Caution should be exercised in the presence of hepatic

impairment or moderate renal impairment, occlusive vascular disease, in children with atopy, and in individuals who are slow metabolizers of CYP2D6 or those who use CYP2D6 inhibitors. Patients with thyroid disease who are receiving thyroid hormones should not take Multi-Action ACTIFED Dry Coughs unless directed by a physician. Patients with acute or chronic asthma, persistent or chronic cough such as in chronic bronchitis or emphysema, cough that is accompanied by excessive secretions, difficulty in urination, urinary retention, prostatic hyperplasia, and susceptibility to angle closure glaucoma are advised to consult a physician before using this product. Discontinue this medication if hallucinations, restlessness, or sleep disturbances occur.
Multi-Action ACTIFED Dry Coughs should not be taken with any other cough and cold medicines. Triprolidine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, and tranquilisers. The use of dextromethorphan with alcohol or other central nervous system depressants may increase their effects on the CNS and consequently result toxicity in relatively smaller doses. While taking this medication, patients should be advised to avoid alcoholic beverages and other centrally acting sedatives.
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, hence, 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. 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
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 with concomitant intake of dextromethorphan and other serotonergic agents, such as SSRIs, drugs which impair the metabolism of serotonin (including 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 5ml of this medicine is equivalent to less than 6 ml of beer or 3 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- It also contains 5 mg sodium benzoate (E211) per 5 ml of this product

- Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).
- The colouring (Ponceau 4R, E124) may cause allergic reactions
- This medicine contains 2.8 g of sucrose per 5 ml. This should be considered in patients with diabetes mellitus.
- It contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say, essentially 'sodium-free'.
- It also contains 1 g sorbitol in each 5 ml. The additive effect of concomitantly administered sorbitol- or fructose-containing medicinal products and dietary intake of sorbitol (or fructose) should be considered as the sorbitol content may affect the bioavailability of other concomitantly and orally administered products. Sorbitol may also cause gastrointestinal discomfort and mild laxative effect.

**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 (in men whom prostatic enlargement could have been an important predisposing factor).
*Rare*: blood disorder, hypersensitivity (cross-sensitivity 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.
*Please refer to Summary of Product Characteristics for detailed information.*
**RRP (ex-VAT):** 100ml: £5.88
**Legal category:** P.
**PL holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK
**PL number**:15513/0010.
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