Product Information for Multi-Action ACTIFED Tablets, NON-DROWSY SINUTAB

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 2.5 mg, pseudoephedrine hydrochloride 60 mg.
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 to 6 hours (maximum of 4 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 pseudoephedrine, triprolidine, or to any of the product's excipients; cardiovascular disease including 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 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.
Precautions:
May cause drowsiness. This product should not be used to sedate a child. This product contains lactose monohydrate; patients with hereditary problems of galactose intolerance, total lactase deficiency, or glucose malabsorption should not take this medicine. Caution should be exercised in the presence of hepatic or moderate renal impairment. Use with caution in occlusive vascular disease, acute or chronic asthma, chronic bronchitis, or emphysema. Patients with thyroid disease who are receiving thyroid hormones should not take Multi-Action ACTIFED Tablets, unless directed by a physician. Patients with difficulty in urination, urinary retention, prostatic hyperplasia, or susceptibility to angle closure are advised to consult a physician before using this product. This product should be discontinued if hallucinations, restlessness, or sleep disturbances occur.
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.
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.
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.

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. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Triprolidine is excreted in breast milk, it has been estimated that approximately 0.06 to 0.2% of a single 2.5 mg dose of triprolidine ingested by a nursing mother will be excreted in the breast-milk over 24 hours.

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).
Rare: blood disorder, hypersensitivity (cross-sensitivity with other sympathomimetics), confusional state, depression, sleep disorder, extrapyramidal disorder, seizure, tremor, palpitations, hypotension, liver disorder.
Not known: anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, cerebrovascular accident, paraesthesia, 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, abdominal discomfort, ischaemic colitis, vomiting, angioedema, pruritus, rash, severe skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, fatigue.
Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 12's £5.33
Legal category: P

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL number: PL 15513/0014.
Date of prep: 18 MAY 2025

NON-DROWSY SINUTAB (pseudoephedrine hydrochloride, paracetamol) Product Information

Presentation:
Tablets containing 30 mg pseudoephedrine hydrochloride and 500 mg paracetamol.
Uses:
Symptomatic relief of conditions where congestion of the mucous membranes of the upper respiratory tract, especially nasal mucosa, and sinuses, is accompanied by mild to moderate pain or pyrexia, including the common cold and influenza, sinusitis, nasopharyngitis, allergic rhinitis, and vasomotor rhinitis.
Dosage:
Adults and children 16 years and over: Two tablets every four to six hours, up to four times a day (maximum daily dose of 8 tablets). *Children 12 years to 15 years:* One tablet every four to six hours, up to four times a day (maximum daily dose of 4 tablets).
Contraindications:
This product should not be used in children under 12 years of age. This product is contraindicated in individuals with known hypersensitivity to paracetamol, pseudoephedrine, or any of the excipients; cardiovascular disease including 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 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.
Precautions:
Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate renal impairment (particularly if accompanied by cardiovascular disease), and in occlusive vascular disease. Patients with the following conditions should be advised to consult a physician before using this product: difficulty in urination, urinary retention and/or prostatic hyperplasia, patients with thyroid disease who are receiving thyroid hormones. This product should be stopped if patients experience hallucinations, restlessness, sleep disturbances. Pseudoephedrine carries the risk of abuse and increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. Do not exceed the recommended maximum dose and treatment duration.
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, this product should be discontinued, and appropriate measures should be 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.
Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism), who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended.

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. The safety of pseudoephedrine in pregnancy has not been established. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known. Paracetamol is excreted in breast milk but not in a clinically significant amount. Maternal ingestion of therapeutic doses of paracetamol does not appear to present a risk to the infant.

Side effects:

Very common: headache.
Common: insomnia, nervousness, dizziness, dry mouth, nausea.
Uncommon: nephropathy toxic
*Rare***:** hypersensitivity (cross-sensitivity with other sympathomimetics), hepatic necrosis, rash.
*Not known***:** blood disorders, blood dyscrasias (including agranulocytosis and thrombocytopenia), 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, somnolence, tremor, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension, abdominal pain, diarrhoea, ischaemic colitis, vomiting, angioedema, fixed eruption, pruritus, rash pruritic, severe skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, renal papillary necrosis (after prolonged administration), urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor), high anion gap metabolic acidosis.
Please refer to Summary of Product Characteristics for detailed information

RRP (ex VAT): £6.04
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
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