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, Extrapyramidal disorder, Seizure, Tremor, Palpitations, Hypotension, Liver disorder.

RRP (ex-VAT): 12s: £4.83

Legal category: P

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

PL number: 15513/0014.

Date of preparation: 28 MAR 2022

Non-Drowsy Sinutab (30 mg Pseudoephedrine Hydrochloride, 500 mg Paracetamol) Product Information

Presentation:
Tablets.

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. Children 12 years to 15 years: One tablets every four to six hours, up to four times a day.

Contraindications:
Use in children under the age of 12 years. Hypersensitivity to paracetamol, pseudoephedrine or any of the excipients. Concomitant use of other sympathomimetic decongestants, beta-blockers or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. The concomitant use of MAOIs may cause a rise in blood pressure or hypertensive crisis. Cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe renal impairment.

Precautions:
Patients experiencing difficulty in urination due to enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician. Caution should be exercised when using the product in the presence of severe hepatic impairment (particularly if accompanied by cardiovascular disease), or moderate to severe renal impairment, or in occlusive vascular disease. If any of the following occur, the product should be stopped: hallucinations, restlessness, sleep disturbances. 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, the product should be discontinued. Cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued 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 reports of posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Pseudoephedrine should be discontinued if symptoms of these conditions develop.
Avoid taking this product with other paracetamol-containing products. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors.

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.

Side effects:
Very common: headache.
Common: insomnia, nervousness, headache, dizziness, dry mouth, nausea.
*Rare***:** Hypersensitivity (cross-sensitivity may occur with other sympathomimetics), Hepatic necrosis, Rash.
*Not known***:** Blood disorders, blood dyscrasias (including agranulocytosis and thrombocytopenia) have been reported following paracetamol use, but were not necessarily causally related to the drug, 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 whom prostatic enlargement could have been an important predisposing factor)
Please refer to Summary of Product Characteristics for detailed information
RRP (ex VAT): £5.41
Legal category: P
PL Holder: McNeil Products Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK
PL Number: PL 15513/0027
Date of prep: 06 September 2022