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.

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): £5.80

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