

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

Sudafed Plus Blocked Nose 1mg/50mg/ml Nasal Spray Solution (Xylometazoline Hydrochloride and Dexpanthenol) Product Information

Presentation:

Spray pump bottle containing 10ml of a clear, colourless to slightly yellowish solution. Each 1 ml of nasal spray contains 1 mg xylometazoline hydrochloride and 50 mg dexpanthenol.

Uses:

Symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies.

Dosage:

Adults and children 12 years and over: One spray into each nostril up to 3 times a day, Maximum daily dose: 3 sprays in 24 hours. Use for more than 7 consecutive days is not recommended.

Children under 12 years: Do not give to children under 12 years of age.

Contraindications:

Contraindicated in children under 12 years of age. Also contraindicated in individuals with the following conditions: hypersensitivity to the active substances or to any of the excipients listed, dry inflammation of the nasal mucosa (rhinitis sicca), taking or have taken monoamine oxidase inhibitors within the preceding two weeks, and with a history of transsphenoidal hypophysectomy or other surgical interventions which expose the dura mater.

Precautions:

Use with caution due to minimal systemic absorption with topically applied imidazoline sympathomimetics such as xylometazoline. Use of this product is recommended only after a careful assessment of the risks and benefits for cases of increased intraocular pressure, especially narrow-angle glaucoma, serious heart and circulatory diseases (e.g. coronary heart disease, hypertension), phaeochromocytoma, metabolic disorders (e.g., hyperthyroidism, diabetes), porphyria, and prostate hyperplasia. Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

Use during chronic rhinitis may only be carried out under medical supervision. Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. Direct contact of the medicinal product with the eyes should be avoided.

Interactions:

Concomitant use with other sympathomimetics, antihypertensive agents, and medicines which potentially increase blood pressure should be avoided.

Pregnancy and Lactation:

Not recommended

Side effects:

Uncommon: hypersensitivity reaction (angioedema, skin rash, pruritus),

Rare: palpitations, tachycardia, hypertension.

Very rare: restlessness, insomnia, hallucinations, fatigue (drowsiness, sedation), headache, convulsions, arrhythmias, rebound congestion, nosebleed

Not known: sneezing, burning and dryness of the nasal mucosa.

Reporting of side-effects: You can report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

RRP (ex VAT): £5.84

Legal category: P

PL Holder: McNeil Products Ltd., 50 - 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG, UK

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