

Prescribing Information –Mucodyne

Please refer to the Summary of Product Characteristics for full prescribing information.

Presentation: Mucodyne Capsules containing carbocisteine 375 mg. Mucodyne Syrup containing carbocisteine 250 mg/5 ml. Mucodyne Paediatric Syrup containing carbocisteine 125 mg/5 ml.

Indication: Carbocisteine is a mucolytic agent for the adjunctive therapy of respiratory tract disorders characterised by excessive, viscous mucus, including chronic obstructive airways disease.

Dosage and method of administration: For oral administration.

Adults including the elderly: Initial daily dosage of 2250 mg carbocisteine in divided doses, reducing to 1500 mg daily in divided doses when a satisfactory response is obtained. For Syrup 15ml tds should be reduced to 10ml tds.

Children (use Paediatric Syrup): 5 - 12 years: 10 ml three times daily. Children 2 - 5 years: 2.5 - 5 ml four times daily.

Contraindications: Hypersensitivity to the active substance. Active peptic ulceration. *Paediatric syrup:* contraindicated for use in children less than 2 years of age.

Warnings and Precautions: Not recommended during the first trimester of pregnancy. Effects during lactation not known. *Capsules:* not suitable for use in patients with rare hereditary problems of galactose intolerance, the Lapp Lactase deficiency or glucose-galactose malabsorption. *Syrup and Paediatric syrup:* not suitable for use in patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency.

Side effects: There have been rare reports of skin rashes, allergic skin eruptions, anaphylactic reactions and fixed drug eruption with all presentations of Mucodyne. Rare reports of gastrointestinal bleeding occurring during treatment with Mucodyne Capsules and Syrup only.

Legal category: POM

Product Licence Numbers and NHS cost

Mucodyne Capsules: PL 04425/0203 Pack 120 capsules £18.98

Mucodyne Syrup: PL 04425/0204 Bottle of 300ml £6.59

Mucodyne Paediatric Syrup: PL 04425/0205 Bottle of 300ml £5.08

Product Licence holder: Sanofi-Aventis, One Onslow Street, Guildford, Surrey, GU1 4YS. Further information is available from the Medical Information department at the address above or on Tel; 01483 505515

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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 the sanofi-aventis Drug Safety Department on 01483 505515.