

**Tusca[®]**Guaiphenesin, Pseudoephedrine HCl and Triprolidine HCl
Expectorant**COMPOSITION**

Tusca[®] Syrup : Each 5 ml syrup contains Guaiphenesin BP 100 mg, Pseudoephedrine hydrochloride BP 30 mg, Triprolidine hydrochloride BP 1.25 mg.

PHARMACOLOGY

Tusca[®] syrup is a mixture of expectorant, bronchodilator decongestant and antihistamine agent. Triprolidine in Tusca[®] provides symptomatic relief in conditions believed to depend wholly or partly upon the triggered release of histamine. It is a potent competitive histamine H₁ receptor antagonist of the pyrrolidine class with mild central nervous system depressant properties which may cause drowsiness. Pseudoephedrine has direct and indirect sympathomimetic activity and is an effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the nervous system. Guaiphenesin has expectorant action. It is thought to reduce sputum viscosity by increasing the volume and water content of the bronchial secretion. Thereby facilitating the expectoration of sputum.

Tusca[®] syrup is absorbed from the GI tract and excreted in the urine. Guaiphenesin is metabolised in the liver and excreted in the urine. Pseudoephedrine is largely excreted unchanged in the urine together with small amounts of its hepatic metabolites and triprolidine is metabolised in the liver and excreted usually as metabolites in the urine.

INDICATION

Tusca[®] is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough which benefits from the administration of a nasal decongestant, a histamine H₁ receptor antagonist and an expectorant combination.

DOSAGE AND ADMINISTRATION

Adults: 2 teaspoonful three times a day.

Children: Over 12 years : 2 teaspoonful three times a day.

6-12 years : 1 teaspoonful three times a day.

2-6 years : 1/2 teaspoonful three times a day.

A physician's advice should be obtained before administering Tusca[®] to children less than 2 years.

Tusca[®]

Tusca[®] syrup may be diluted 1: 1 or 1:3 with unpreserved syrup BP, and these dilutions have a shelf life of 4 weeks if stored at 25°C.

CONTRAINDICATION AND PRECAUTION

Tusca[®] is contraindicated in patients with a known hypersensitivity to guaiphenesin , pseudoephedrine or triprolidine. Contraindicated in persons under treatment with monoamine oxidase inhibitor within 2 weeks of stopping such treatment. Tusca[®] is contraindicated in patients with severe hypertension or severe coronary artery disease.

Tusca[®] may cause drowsiness and impair performance in tests of auditory vigilance. Patients should not drive or operate machinery until they have determined their own response. Although there are no objective data, users of Tusca[®] should avoid the concomitant use of alcohol or other centrally acting sedatives.

Although pseudoephedrine has virtually no blood pressure effect in patients with normal blood pressure Tusca[®] should be used with caution in patients taking antihypertensive agents, tricyclic antidepressants or other sympathomimetic agents such as decongestant, appetite suppressants and amphetamine like psychostimulants. The effects of a single dose of Tusca[®] on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. As with other sympathomimetic agents caution should be exercised in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement. Tusca[®] should not be used for persistent or chronic cough such as occurs with asthma, or emphysema or where cough is accompanied by excessive secretions unless directed by a physician.

SIDE EFFECT

Central nervous system (CNS) depression or excitation may occur, drowsiness being reported most frequently. Sleep disturbance and rarely hallucination have been reported. Skin rashes with or without irritation, tachycardia, dryness of mouth, nose and throat have occasionally been reported. Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important predisposing factor.

DRUG INTERACTION

Concomitant use of Tusca® with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines may occasionally cause a rise in blood pressure. Because of its pseudoephedrine content, Tusca® partially reverse the hypotensive action of drugs which interfere with sympathetic activity including guanethidine, methyldopa, alpha-adrenergic blocking agents.

USE IN PREGNANCY AND LACTATION

Although pseudoephedrine, triprolidine and guaiphenesin have been in widespread use of many years without apparent ill consequence, there are no specific data on their use during pregnancy. Caution should therefore be exercised by balancing the potential benefits of treatment of the mother against any possible hazards to the developing fetus.

STORAGE CONDITION

Store below 25°C. Do not refrigerate. Protect from light.

HOW SUPPLIED

Tusca® 100 ml syrup : Bottle containing a measuring cup and 100 ml syrup.

