For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Terbutaline Sulphate, Ambroxol HCl & Guaiphenesin Liquid
(Brand Name: TUSQ®-X+ Liquid)

2. Qualitative and Quantitative Composition

Each 5 ml contains:
Terbutaline Sulphate IP …… 1.25 mg.
Ambroxol Hydrochloride IP …… 15 mg.
Guaiphenesin IP ……... 50 mg.
Flavoured Mentholated base …….……. q.s.
Colours : Brilliant Blue FCF & Tartrazine

3. Dosage Form and Strength

Dosage Form: Liquid.
Dosage Strength: Terbutaline sulphate 1.25 mg, Ambroxol hydrochloride 15 mg, Guaiphenesin 50 mg per 5 ml.

4. Clinical Particulars

4.1 Therapeutic Indication

TUSQ-X+ Liquid is indicated for the symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
TUSQ-X+ Liquid is also indicated for the treatment of productive cough associated with lower respiratory tract infections (such as acute bronchitis, pneumonia, and tuberculosis) and chronic lung diseases (such as chronic bronchitis and asthma).

4.2Posology and Method of Administration

For oral administration.

- **Adults and children above 12 years:** 10 ml to be administered 3 times daily.
- **Children between 6 to 12 years:** 5 ml to be administered 3 times daily.
- **Children between 2 to 6 years:** 2.5 ml to be administered 3 times daily.

Do not exceed the stated dose. TUSQ-X+ Liquid should not be used with other cough and cold medicines. TUSQ-X+ Liquid should be taken with food.
Or, as prescribed by the physician.

4.3Contraindications

TUSQ-X+ Liquid is contraindicated in the following:

- Hypersensitivity to ambroxol, terbutaline, guaiphenesin, or to any component of the formulation.
- In cardiac disease and in patients with significant risk factors for myocardial ischemia.
- Thyrotoxicosis.

4.4Special Warnings and Precautions for Use

Terbutaline Sulphate

Like all other beta 2-agonists, use of terbutaline is contraindicated in patients with thyrotoxicosis.

Immediate hypersensitivity reactions and exacerbation of bronchospasm have been reported after terbutaline administration.

Cardiovascular effects may be seen with sympathomimetic drugs, including terbutaline. There is some evidence from post-marketing data and published literature of myocardial ischemia associated with beta-agonists. Terbutaline, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of terbutaline at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiogram (ECG) changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Due to the positive inotropic effect of beta 2-agonists, these drugs should not be used in patients with hypertrophic cardiomyopathy. Terbutaline, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, including ischemic heart disease, hypertension, and cardiac arrhythmias; hyperthyroidism; diabetes mellitus; hypersensitivity to sympathomimetic amines; and convulsive disorders. Significant changes in systolic and diastolic blood pressure have been observed and may be expected to occur in some patients after use of any beta-adrenergic bronchodilators.

Patients with underlying severe heart disease (e.g., ischemic heart disease, arrhythmia or severe heart failure) should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Due to the hyperglycemic effects of beta 2-agonists, additional blood glucose controls are recommended initially in diabetic patients.

Potentially serious hypokalaemia may result from beta 2-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalemic effect may be potentiated by concomitant treatments. It is recommended that serum potassium levels be monitored in such situations.

There have been rare reports of seizures in patients receiving terbutaline. Seizures did not recur in these patients after the drug was discontinued.

Ambroxol Hydrochloride

Ambroxol should be used with caution in patients with gastric ulceration.

Care to be taken to avoid contact with eye, skin, serious ingestion or inhalation.

In patients with symptoms of chronic impairment of mucus production and/or clearance, ambroxol should be used with caution. In patients with malignant cilia syndrome, the advantages of mucus liquefaction should be carefully weighed against the risk of a secretory obstruction.

The secretolytic effect of ambroxol may be supported by adequate fluid intake.

The simultaneous administration of antitussives should definitely be avoided due to the risk of secretory obstruction.

There have been very rare reports of severe skin lesions such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN, Lyell's Syndrome) in temporal association with the administration of mucolytic substances such as ambroxol hydrochloride. Mostly these could be explained by the severity of the underlying disease or concomitant medication. During the early phase of a SJS or TEN, a patient may first experience nonspecific influenza-like prodromal symptoms e.g., fever, body ache, rhinitis, cough, and sore throat. If new skin or mucosal lesions occur, treatment with ambroxol hydrochloride should be discontinued as a precaution.

Guaiphenesin

Caution should be exercised in the presence of severe renal or severe hepatic impairment. The concomitant use of cough suppressants is not recommended. Guaiphenesin should not be administered in patients with rare hereditary problems of fructose intolerance. Guaiphenesin is considered to be unsafe in patients with porphyria.

4.5Drug Interactions

Terbutaline Sulphate

Beta-blockers: Beta-blocking agents (including eye preparations), especially the non-selective ones such as propranolol, may partially or totally inhibit the effect of beta-stimulants. Therefore terbutaline preparations and non-selective beta-blockers should not normally be administered concurrently.

Sympathomimetic agents: Terbutaline should be used with caution in patients receiving other sympathomimetics.

Monoamine oxidase (MAO) inhibitors or tricyclic antidepressants: Terbutaline should be administered with extreme caution to patients being treated with MAO inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, since the action of terbutaline on the vascular system may be potentiated.

Halogenated anesthetics: Halothane anaesthesia should be avoided during beta 2-agonist treatment, since it increases the risk of cardiac arrhythmias. Other halogenated anesthetics should be used cautiously together with beta 2-agonists.

Potassium depleting agents (e.g., diuretics, methyl xanthines, corticosteroids): Owing to the hypokalemic effect of beta-agonists, concurrent administration of terbutaline with serum

potassium-depleting agents known to exacerbate the risk of hypokalemia, such as diuretics, methyl xanthines and corticosteroids, should be administered cautiously after careful evaluation of the benefits and risks with special regard to the increased risk of cardiac arrhythmias arising as a result of hypokalaemia. Hypokalaemia also predisposes to digoxin toxicity.

Ambroxol Hydrochloride

Antibiotics: After using ambroxol, the concentrations of antibiotics such as amoxycillin, cefuroxime, and erythromycin in bronchial secretions and sputum are increased.

Antitussives: Concomitant administration of antitussives may impair the expectoration of liquefied bronchial mucus due to inhibition of the cough reflex and cause accumalation of secretions.

No clinically relevant interactions with other medications have been reported.

Guaiphenesin

Paracetamol: Guaiphenesin may increase the rate of absorption of paracetamol.

Laboratory tests: If urine is collected within 24 hours of a dose of guaiphenesin, its metabolite may cause a color interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

4.6Use in Special Populations

Pregnant Women

No teratogenic effects have been observed with terbutaline in animals or in patients. Transient hypoglycaemia has been reported in newborn preterm infants after maternal beta 2-agonist treatment.

Ambroxol crosses the placenta. Animal studies do not show either direct or indirect harmful effects on pregnancy, embryofoetal development, parturition or postnatal development. Comprehensive controlled studies in pregnant women after the 28^{th} week have not shown any harmful effects on the foetus. Use of ambroxol during the first trimester of pregnancy is not recommended.

Guaiphenesin has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy.

TUSQ-X+ Liquid should not be used during the first trimester of pregnancy. Caution is advised when TUSQ-X+ Liquid is used during second and third trimesters of pregnancy.

Lactating Women

Terbutaline and ambroxol are excreted in breast milk. However their adverse effects on the infant are unlikely. There is no information regarding effect of guaiphenesin on lactation. Use of TUSQ-X+ Liquid is not recommended during lactation and thus, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Patients

Safety and efficacy of this formulation in neonates and children below 2 years of age has not been established. Thus, TUSQ-X+ Liquid is not recommended for use in paediatric patients below 2 years of age. For dosage in children above 2 years of age, please refer 'Posology and Method of Administration' section.

Geriatric Patients

Elderly patients with normal renal and hepatic function may be given the same dose as recommended for adults. Terbutaline is known to be excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment Patients

In severe renal impairment, accumulation of ambroxol metabolites has been reported. Therefore, caution should be exercised while using TUSQ-X+ Liquid in patients with significant renal dysfunction. Dose should be reduced or the dosing interval must be extended in patients with severe renal impairment.

Hepatic Impairment Patients

In severe hepatic impairment, TUSQ-X+ Liquid should be used with caution.

4.7Effect on Ability to Drive and Use Machines

Studies on the effects on the ability to drive and use machines have not been performed with TUSQ-X+ Liquid. Terbutaline sulphate or ambroxol hydrochloride or guaiphenesin has no or negligible influence on the ability to drive and use machines. However, caution should be exercised if patients experience dizziness. If affected by dizziness, patients should avoid potentially hazardous tasks such as driving a vehicle or operating machinery.

4.8Undesirable Effects

TUSQ-X+ Liquid is generally well tolerated. Adverse events are generally rare, transient, and mild in nature. Following are the adverse effects reported with individual active ingredients of this formulation:

Terbutaline Sulphate

The common adverse reactions to terbutaline are tremor, headache, tachycardia, palpitations, muscle spasms, nervousness, somnolence, dizziness, anxiety, insomnia, ventricular extrasystoles, vasodilation, nausea, dry mouth, asthenia, and sweating. Hypokalaemia has also been reported.

The adverse effects reported in less than 1% of patients are hallucinations, rash, paresthesia, hypertonia, muscle cramps, vomiting. There have been rare reports of elevation of liver enzymes and of hypersensitivity vasculitis. Rare cases of arrhythmias (e.g., atrial fibrillation, supraventricular tachycardia, and extrasystoles), myocardial ischemia, peripheral vasodilation, hypersensitivity reactions including angioedema, bronchospasm, hypotension,

nausea, mouth and throat irritation, sleep disorder, behavioural disturbances such as agitation and restlessness, paradoxical bronchospasm, urticaria, and rash may occur with terbutaline.

Ambroxol Hydrochloride

Occasional gastrointestinal side effects may occur, but these are normally mild. With prolonged administration in large doses, pain in epigastrium, nausea, vomiting can appear.
Additional adverse effects reported rarely with ambroxol include:
Gastrointestinal disorders: Dyspepsia, nausea, vomiting, diarrhoea, and abdominal pain.
Respiratory, mediastinal, and thoracic disorders: Oral and pharyngeal hypoaesthesia, dry mouth, and dry throat.
Nervous system disorders: Dysgeusia (e.g., changed taste).
Immune system disorders: Anaphylactic reactions including anaphylactic shock.
Skin and subcutaneous tissue disorders: Angioedema, rash, urticaria, pruritus, and other hypersensitivity reactions.
Allergic reactions: In patients having hypersensitivity to ambroxol, skin rash, nettle-rash, and angioneurotic oedema may occur.

Guaiphenesin

Side effects resulting from guaiphenesin administration are very rare. Guaiphenesin has occasionally been reported to cause gastrointestinal discomfort, nausea and vomiting, particularly in very high doses. Hypersensitivity reactions may occur. Allergic reactions, angioedema, anaphylactic reactions, dyspnoea (reported in association with other symptoms of hypersensitivity), nausea, vomiting, abdominal discomfort, rash, and urticaria have been reported very rarely with the use of guaiphenesin.

4.9Overdose

Terbutaline Sulphate

Possible signs and symptoms include headache, anxiety, tremor, nausea, tonic cramps, palpitations, tachycardia, and arrhythmia. A fall in blood pressure may occur. Laboratory findings such as hypokalaemia, hyperglycemia, and lactic acidosis may occur sometimes.
Treatment includes gastric lavage and administration of activated charcoal. Determination of acid-base balance, blood sugar and electrolytes (particularly serum potassium) level is recommended. Monitoring of the heart rate and rhythm and blood pressure is also advised. Metabolic changes should be corrected. A cardioselective beta-blocker (e.g., metoprolol) is recommended for the treatment of arrhythmias causing hemodynamic deterioration. The beta-blocker should be used with care because of the possibility of inducing bronchoconstriction. Caution should be exercised in patients with a history of bronchospasm. If the beta 2-mediated reduction in the peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

Ambroxol Hydrochloride

No overdose has been reported with ambroxol in humans. Acute potential health effects include skin irritation, eye irritation, respiratory tract irritation, gastrointestinal tract irritation

with decreased motility or constipation, ulceration or bleeding from the stomach or duodenum, and peritonitis. It may even affect behavior/central nervous system (tremor, convulsions, ataxia, and somnolence), respiration (dyspnea, respiratory stimulation), liver, blood (changes in white blood cell count) and urinary system. If overdose occurs, supportive and symptomatic treatment should be provided.

Guaiphenesin

The effects of acute toxicity from guaiphenesin may include gastrointestinal discomfort, nausea, vomiting, and drowsiness. The drug is, however, rapidly metabolized and excreted in the urine. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated. Patients should be kept under observation and symptomatic and supportive treatment is advised.

5. Pharmacological Properties

5.1 Mechanism of Action

Terbutaline Sulphate

Terbutaline is a selective beta 2-adrenergic agonist which predominantly stimulates beta 2-receptors, thus producing relaxation of bronchial smooth muscle.

The pharmacologic effects of beta-adrenergic agonist drugs, including terbutaline, are in part attributable to beta-adrenergic receptor-based stimulation of intracellular adenyl cyclase, the enzyme that catalyses the conversion of adenosine triphosphate (ATP) to cyclic-3′,5′-adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels are associated with relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially mast cells.

Ambroxol Hydrochloride

Ambroxol causes an increase of secretion in the respiratory tract. It enhances pulmonary surfactant production and stimulates ciliary activity. These actions result in improved mucus flow and transport (mucociliary clearance). Improvement of mucociliary clearance has been shown in clinical pharmacologic studies. Enhancement of fluid secretion and mucociliary clearance facilitates expectoration and reduces cough.

Guaiphenesin

Guaiphenesin is thought to exert its expectorant action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Another possible mechanism by which it acts is by increasing the water bonding in the sputum, thereby decreasing its viscosity and leading to an increase in mucokinesis.

Other actions may include stimulation of vagal nerve endings in bronchial secretory glands and stimulating certain centers in the brain, which in turn enhance respiratory fluid flow.

5.2Pharmacodynamic Properties

Terbutaline Sulphate

Terbutaline sulphate is a direct-acting sympathomimetic agent with mainly beta-adrenergic activity. Terbutaline produces bronchodilation, increase in mucociliary clearance, suppression of oedema, and anti-allergic effects. Due to its bronchodilating properties, terbutaline is given in respiratory disorders such as reversible airway obstruction, as occurs in asthma and in some patients with chronic obstructive pulmonary disease.

Ambroxol Hydrochloride

Ambroxol is the active metabolite of bromhexine. Ambroxol is more effective than bromhexine and is non-toxic and well tolerated. Ambroxol possesses mucolytic, mucokinetic (improvement in mucus transport), and secretolytic properties. It promotes the removal of tenacious secretions from the respiratory tract and reduces mucus stasis (arresting the secretion of mucus). Ambroxol also exhibits anti-oxidant activity.

Guaiphenesin

Guaiphenesin produces its expectorant action by increasing the volume of respiratory tract fluid and reducing the viscosity of tenacious secretions.

5.3Pharmacokinetic Properties

Terbutaline Sulphate

Fasting bioavailability after oral doses is reported to be about 14 to 15% and is reduced by food (average 10%). Terbutaline undergoes extensive first-pass metabolism by sulphate (and some glucuronide) conjugation in the liver and the gut wall. It is excreted in the urine and faeces, partly as the inactive sulphate conjugate and partly as unchanged terbutaline, the ratio depending upon the route by which it is given. The terminal half-life after single and multiple dosing is reported to be between 16 and 20 hours.

Ambroxol Hydrochloride

Ambroxol is absorbed rapidly and almost completely after oral administration. Oral bioavailability is approximately 60% owing to the first-pass effect. Bioavailability of ambroxol hydrochloride is not affected by food. Plasma concentrations are in a linear relationship to the dose. Peak plasma levels are attained after 0.5 to 3 hours.

Plasma protein binding is around 90% in the therapeutic range. After oral, intravenous, and intramuscular administration, ambroxol is distributed swiftly and extensively from the blood into the tissues. The highest active ingredient concentrations have been measured in the lung.

Ambroxol is metabolized in the liver mainly by conjugation. Studies in human liver microsomes showed that CYP3A4 is the predominant isoform for ambroxol metabolism.

Around 30% of an oral dose is eliminated via the first-pass effect. The terminal half-life is about 10 hours. Total clearance is 660 ml/min approximately, and renal clearance is 8% of the total clearance.

Guaiphenesin

Guaiphenesin is well absorbed from the gastrointestinal tract following oral administration. However, limited information is available regarding its pharmacokinetics. After the administration of 600 mg guaiphenesin to healthy adult volunteers, the C_{max} was approximately 1.4 mcg/ml, T_{max} occurred approximately 15 minutes after drug administration, t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours. Guaiphenesin appears to undergo both oxidation and demethylation.

6. Nonclinical Properties

6.1 Animal Toxicology

Terbutaline Sulphate

Toxicity: The major toxic effect of terbutaline, observed in toxicological studies in rats and dogs at exposures in excess of maximum human exposure, is focal myocardial necrosis. This type of cardiotoxicity is a well-known pharmacological manifestation seen after the administration of high doses of beta$_2$-agonists.

Carcinogenesis: In a 2-year study in Sprague-Dawley rats, terbutaline sulfate caused a significant and dose-related increase in the incidence of benign uterine leiomyomas (of the mesovarium) at dietary doses of 50 mg/kg and above (approximately 810 times the maximum recommended daily subcutaneous (s.c.) dose for adults on a mg/m^2 basis). In a 21-month study in CD-1 mice, terbutaline sulfate showed no evidence of tumorigenicity at dietary doses up to 200 mg/kg (approximately 1,600 times the maximum recommended daily s.c. dose for adults on a mg/m^2 basis).

Mutagenesis: The mutagenicity potential of terbutaline sulfate has not been determined.

Impairment of Fertility: Reproduction studies in rats using terbutaline sulfate demonstrated no impairment of fertility at oral doses up to 50 mg/kg (approximately 810 times the maximum recommended daily s.c. dose for adults on a mg/m^2 basis).

Teratogenicity: A reproduction study in Sprague-Dawley rats revealed terbutaline sulfate was not teratogenic when administered orally at doses up to 50 mg/kg (approximately 810 times the maximum recommended daily s.c. dose for adults on a mg/m^2 basis). A reproduction study in New Zealand white rabbits revealed terbutaline sulfate was not teratogenic when administered orally at doses up to 50 mg/kg (approximately 1,600 times the maximum recommended daily s.c. dose for adults on a mg/m^2 basis).

Ambroxol Hydrochloride

Toxicity: Ambroxol hydrochloride has a low index for acute toxicity. In repeat-dose studies, oral doses of 150 mg/kg/day (mouse, 4 weeks), 50 mg/kg/day (rat, 52 and 78 weeks), 40 mg/kg/day (rabbit, 26 weeks) and 10 mg/kg/day (dog, 52 weeks) were the no-observed adverse effect level (NOAEL). No toxicological target organs were detected. Four week intravenous toxicity studies with ambroxol hydrochloride in rats (4, 16 and 64 mg/kg/day) and in dogs (45, 90 and 120 mg/kg/day (infusion 3 h/day)) showed no severe local and systemic toxicity including histopathology. All adverse effects were reversible.

At 500 mg/kg/day, ambroxol hydrochloride was slightly toxic for dams and pups, as shown by a retarded body-weight development and reduced litter size.

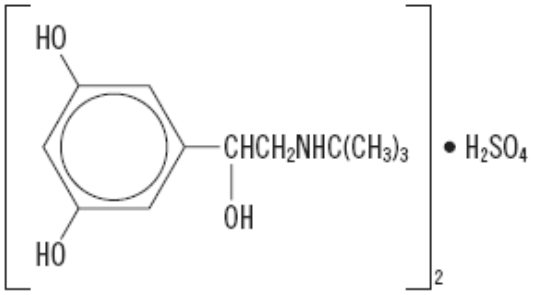
Carcinogenicity: Ambroxol hydrochloride did not show any tumorigenic potential in carcinogenicity studies in mice (50, 200 and 800 mg/kg/day) and rats (65, 250 and 1000 mg/kg/day) when treated with a dietary admixture for 105 and 116 weeks, respectively.
Mutagenesis: Genotoxicity studies *in vitro* (Ames and chromosome aberration test) and *in vivo* (mouse micronucleus test) did not reveal any mutagenic potential of ambroxol hydrochloride.
Impairment of Fertility: The fertility of male and female rats was not affected up to 500 mg/kg/day. The NOAEL in the peri- and post-natal development study was 50 mg/kg/day.
Teratogenicity: Ambroxol hydrochloride was neither embryotoxic nor teratogenic when tested at oral doses up to 3000 mg/kg/day in rats and up to 200 mg/kg/day in rabbits.

Guaiphenesin
There is no relevant information available.

7. Description
TUSQ-X+ Liquid is Green coloured clear liquid with pleasant flavour.

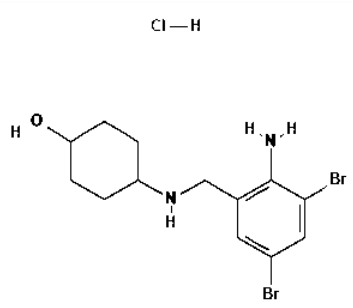
Each 5 ml of TUSQ-X+ Liquid contain 1.25 mg of terbutaline sulphate, 15 mg of ambroxol hydrochloride, and 50 mg of guaiphenesin for oral administration.

Terbutaline Sulphate
Terbutaline sulfate is a beta-adrenergic agonist bronchodilator agent.
Terbutaline sulfate is a white to gray-white crystalline powder.
Molecular Weight: 548.65 g/mol.
Molecular Formula: (C12H19NO3)2 • H2SO4.
Chemical Name: (±)-α-[(tert- butylamino)methyl]-3,5-dihydroxybenzyl alcohol sulfate (2:1) (salt).
Structural Formula:



Ambroxol Hydrochloride
Ambroxol hydrochloride is a metabolite of bromhexine that stimulates mucociliary action and clears the air passages in the respiratory tract.
Molecular Weight: 414.56 g/mol.
Molecular Formula: C13H19Br2ClN2O.
Chemical Name: 4-[(2-amino-3,5-dibromophenyl)methylamino]cyclohexan-1 ol; hydrochloride.

Structural Formula:



Guaiphenesin

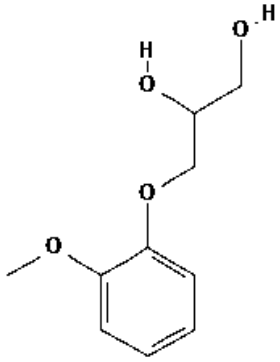
Guaiphenesin, also called as guaifenesin or glyceryl guaiacolate, is an expectorant which promotes or facilitates the removal of secretions from the respiratory tract. Guaiphenesin is a white or slightly gray crystalline substance with a slightly bitter aromatic taste.

Molecular Weight: 198.21 g/mol.

Molecular Formula: C10H14O4.

Chemical Name: 3-(2-methoxyphenoxy)-1,2-propanediol.

Structural Formula:



Inactive ingredients : Sodium Benzoate, Xanthan Gum, Glycerin, Propylene Glycol, Sucralose, Sodium Citrate, Menthol, Lactic Acid, Citric Acid Monohydrate, Colour Tartrazine, Colour Brilliant Blue, Flavour Liquorice, Flavour Mixed Fruit, Flavour Honey, Flavour Tulsi & Purified Water.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 Months

8.3Packaging Information

100 ml bottle with measuring cup.

8.4Storage and Handling Instructions

Store at a temperature not exceeding 30°C. Protect from light.
Keep out of reach of children.

9. Patient Counseling Information

Instructions to Patients

- Instruct patients to ensure the prescribed doses of TUSQ-X+ Liquid is taken as directed. Patients should not exceed the recommended dose or duration of treatment.
- Patients are advised to strictly avoid taking this medicine during first 3 months of pregnancy; for use of this medicine in the last 6 months of pregnancy, patient should consult their doctor.
- Instruct patients not to take this medicine during breastfeeding to neonate/infants unless advised by their doctor.
- Avoid use of this medicine in children below 2 years of age.
- Patients are informed to take this medicine with meal/food.
- Advise patients not to use this medicine with other cough and cold relief products (prescription or over-the- counter - OTC) having similar type of ingredients without consulting to their doctor.

10. Details of Manufacturer

Hema Laboratories Pvt. Ltd.
29, Pharma City, Selaqui Industrial Area, Dehradun – 248 011, Uttarkhand, India.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 19/UA/2007, Date of FDA Product Permission: 11/06/2013

12. Date of Revision

March 2021.

Marketed by:
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.