

*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**

Levosalbutamol, Ambroxol Hydrochloride and Guaiphenesin Syrup

(Brand Name: TUSQ<sup>®</sup>-LS Liquid)

### **2. Qualitative and Quantitative Composition**

Each 5 ml contains:

Levosalbutamol Sulphate IP equivalent to Levosalbutamol ..... 1 mg.

Ambroxol Hydrochloride IP ..... 30 mg.

Guaiphenesin IP ..... 50 mg.

Flavoured Base ..... q.s.

Colour : Tartrazine

### **3. Dosage Form and Strength**

Dosage Form: Liquid.

Dosage Strength: Levosalbutamol 1 mg, ambroxol hydrochloride 30 mg, and guaiphenesin 50 mg per 5 ml.

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indication**

TUSQ-LS Liquid is indicated for the symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.

TUSQ-LS Liquid is also indicated for the treatment of productive cough associated with lower respiratory tract infections – LRTIs (such as acute bronchitis, pneumonia, and tuberculosis) and chronic lung diseases (such as chronic bronchitis and asthma).

#### **4.2 Posology and Method of Administration**

For oral administration.

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

TUSQ-LS Liquid should not be used with other cough and cold medicines. Do not exceed the stated dose. It is recommended to take TUSQ-LS Liquid with food.

Or, as prescribed by the physician.

### **4.3 Contraindications**

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

### **4.4 Special Warnings and Precautions for Use**

#### **Levosalbutamol**

Levosalbutamol, 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 positive inotropic effects, beta 2-agonists should not be used in patients with hypertrophic cardiomyopathy.

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.

#### **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 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 Stevens-Johnson Syndrome 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.

## **4.5 Drug Interactions**

### **Levosalbutamol**

**Other Adrenergic Bronchodilator Drugs:** Other short-acting sympathomimetic bronchodilators or epinephrine should be used with caution with levosalbutamol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.

**Beta-blockers:** Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-agonists such as levosalbutamol, but may also produce severe bronchospasm in asthmatic patients.

**Diuretics:** Diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists. Hence, caution is advised in the co-administration of beta-agonists with non-potassium sparing diuretics.

**Digoxin:** Digoxin levels were demonstrated after single-dose intravenous and oral administration of racemic salbutamol, hence it is advisable to carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and levosalbutamol.

**Monoamine Oxidase (MAO) Inhibitors or Tricyclic Antidepressants:** Levosalbutamol 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, because the action of levosalbutamol on the vascular system may be potentiated.

### **Ambroxol Hydrochloride**

**Antibiotics:** After using ambroxol, the concentrations of antibiotics such as amoxicillin, 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 accumulation 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).

## **4.6 Use in Special Populations**

### **Pregnant Women**

There are no adequate and well-controlled studies of this combination in pregnant women. 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, embryofetal development, parturition or postnatal development. Comprehensive controlled studies in pregnant women after the 28<sup>th</sup> 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-LS Liquid should not be used during the first trimester of pregnancy. Caution is advised when TUSQ-LS Liquid is used during second and third trimesters of pregnancy.

### **Lactating Women**

It is not known whether levosalbutamol is excreted in human milk. Although ambroxol is excreted in the breast milk, adverse effects on the infants are unlikely. There is no information regarding effect of guaiphenesin on lactation. Use of TUSQ-LS Liquid is not recommended during lactation. 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-LS 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. Levosalbutamol is known to be substantially 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-LS 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-LS Liquid should be used with caution.

## **4.7 Effect 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-LS Liquid. Ambroxol hydrochloride or guaiphenesin has no or negligible influence on the ability to drive and use machines. In some individuals, levosalbutamol may cause nervousness, headache, dizziness, fatigue and sleeplessness. Thus, caution should be exercised while taking TUSQ-LS Liquid. If affected by dizziness, patients should avoid potentially hazardous tasks such as driving a vehicle or operating machinery.

## **4.8 Undesirable Effects**

### **Levosalbutamol**

The most frequent side effects are palpitation, fine tremors of the skeletal muscle (particularly the hand) and muscle cramps. The other likely side effects are gastrointestinal disturbances such as nausea, vomiting, burning substernal or epigastric pain and diarrhoea. In some cases nervousness, headache, dizziness, fatigue and sleeplessness may occur.

Potentially serious hypokalaemia may result from beta 2-agonist therapy. This effect may be potentiated by hypoxia. Particular caution is advised in severe asthma; in such cases, monitoring of serum potassium levels is recommended.

### **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.

## **4.9 Overdose**

### **Levosalbutamol**

The expected symptoms with overdose are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the side effects, e.g., angina, hypertension, tachycardia, nervousness, headache, tremor, palpitations, dry mouth, nausea, dizziness, fatigue, and insomnia. Hypokalaemia may also occur. As with all sympathomimetic medications, cardiac arrest and even death may be associated with the abuse of levosalbutamol.

Treatment consists of discontinuation of levosalbutamol together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdose of levosalbutamol.

### **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**

#### **Levosalbutamol**

Levosalbutamol is a selective beta 2-receptor agonist. Levosalbutamol produces bronchodilation through stimulation of beta 2-adrenergic receptors in bronchial smooth muscles, thereby causing relaxation of bronchial muscle fibres. Activation of beta 2-adrenergic receptors on airway smooth muscle leads to the activation of adenylyl cyclase and to an increase in the intracellular concentration of cyclic-3', 5'-adenosine monophosphate (cyclic AMP). The increase in cyclic AMP is associated with the activation of protein kinase A, which in turn, inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in muscle relaxation. Levosalbutamol relaxes the smooth muscles of all airways, from the trachea to the terminal bronchioles.

Levosalbutamol also has a mild anti-inflammatory activity. This is because increased concentration of cyclic AMP is associated with inhibition of the release of inflammatory/bronchoconstrictor mediators from mast cells and eosinophils in the airways.

### **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.

## **5.2 Pharmacodynamic Properties**

### **Levosalbutamol**

Levosalbutamol, the (R)-enantiomer of salbutamol, is a selective beta 2-receptor agonist. Levosalbutamol has approximately 2-fold greater affinity than racemic salbutamol for the beta 2-adrenergic receptor and approximately 100-fold greater affinity than S-salbutamol.

Levosalbutamol is a single isomer beta 2-agonist that differs from racemic salbutamol by elimination of (S)-salbutamol. Levosalbutamol is an effective bronchodilator whose primary mechanism of action is unimpeded by (S)-salbutamol. Therefore, when compared with racemic salbutamol, clinically comparable bronchodilation can be achieved with lesser doses of levosalbutamol. Further, levosalbutamol also substantially decreases beta-mediated side effects associated with racemic salbutamol.

Levosalbutamol has bronchodilator, bronchoprotective, anti-inflammatory, and anti-edematous properties.

### **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.

## **5.3 Pharmacokinetic Properties**

### **Levosalbutamol**

Levosalbutamol [(R)-salbutamol] appears to be stereochemically stable in vivo and does not appear to interconvert metabolically to (S)-salbutamol.

Absorption: Whether administered alone or as the racemate, salbutamol enantiomers are well absorbed from the gastrointestinal tract and have time to maximum drug concentration ( $T_{max}$ ) values ranging from 45 to 360 minutes. The bioavailability of levosalbutamol increases from 9% after a single oral dose to 30% at steady state.

Distribution: The blood to plasma ratio for total salbutamol appears to be near unity ( $0.96 \pm 0.13$ ) in healthy volunteers, suggesting that the total blood clearance of salbutamol is equal to the total plasma clearance once steady state has been reached. Values for binding to blood components, along with similar volumes of distribution for salbutamol enantiomers, suggest that protein binding plays a relatively minor role in the disposition of salbutamol enantiomers.

Metabolism: The intestine is the main site of enantio-selective presystemic metabolism of salbutamol for drug absorbed in the gastrointestinal tract. The clearance of salbutamol by the human body is to a major extent is dependent on sulphate conjugation, in particular after oral dosing. Racemic salbutamol is metabolized by sulphotransferase 1A3 (SULT1A3) to an inactive metabolite in human tissues. However, (R)-salbutamol (levosalbutamol) is sulphated 8-fold faster than (S)-salbutamol because of its higher binding affinity for the enzyme.

Elimination: Calculated renal clearance values for both enantiomers were significantly larger than creatinine clearance, indicating active renal excretion. This leads to relatively higher concentrations of the drug in urine than in plasma.

### **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,  $t_{1/2}$  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**

#### **Levosalbutamol**

**Carcinogenicity:** Although there have been no carcinogenesis studies with levosalbutamol, racemic salbutamol sulfate has been evaluated for its carcinogenic potential. In a 2-year study in Sprague-Dawley rats, dietary administration of racemic salbutamol sulfate resulted in a significant dose-related increase in the incidence of benign leiomyomas of the mesovarium at doses of 2 mg/kg/day and greater. In an 18-month study in CD-1 mice and a 22-month study in the golden hamster, dietary administration of racemic salbutamol sulfate showed no evidence of tumorigenicity. Dietary doses in CD-1 mice were up to 500 mg/kg/day and doses in the golden hamster study were up to 50 mg/kg/day.

**Mutagenesis:** Levosalbutamol HCl was not mutagenic in the Ames test or the CHO/HPRT Mammalian Forward Gene Mutation Assay. Levosalbutamol was not clastogenic in the *in vivo* micronucleus test in mouse bone marrow. Racemic salbutamol sulfate was not clastogenic in an *in vitro* chromosomal aberration assay in CHO cell cultures.

**Impairment of Fertility:** No fertility studies have been conducted with levosalbutamol. Reproduction studies in rats using racemic salbutamol sulfate demonstrated no evidence of impaired fertility at oral doses up to 50 mg/kg/day.

**Teratogenicity:** In animal studies, oral administration of levosalbutamol HCl to pregnant New Zealand White rabbits found no evidence of teratogenicity at doses up to 25 mg/kg/day. However, other studies demonstrated that racemic salbutamol sulfate was teratogenic in mice and rabbits at doses comparable to the human therapeutic range. Pregnant mice administered racemic salbutamol sulfate subcutaneously (s.c.) had a dose-related increased incidence of cleft palate in their fetuses. The drug did not induce cleft palate formation when administered subcutaneously at a dose of 0.025 mg/kg/day. In addition, oral administration of racemic salbutamol sulfate to pregnant rabbits resulted in an increased incidence of cranioschisis in fetuses.

#### **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-LS Liquid is Yellow colored, clear flavored solution.

Each 5 ml of TUSQ-LS Liquid contain 1 mg of levosalbutamol, 30 mg of ambroxol hydrochloride, and 50 mg of guaiphenesin for oral administration.

### **Levosalbutamol**

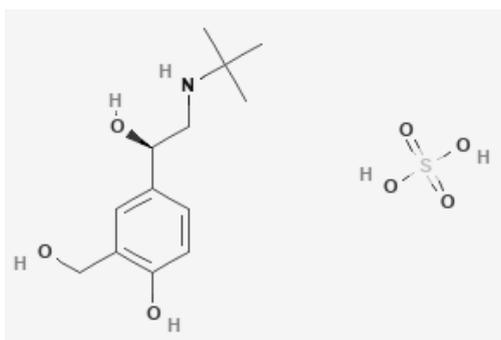
Levosalbutamol, also called as levalbuterol, is a short-acting  $\beta_2$  adrenergic receptor agonist used as a bronchodilator.

Molecular Weight: 337.39 g/mol.

Molecular Formula: C<sub>13</sub>H<sub>23</sub>NO<sub>7</sub>S.

Chemical Name: 4-[(1R)-2-(tert-butylamino)-1-hydroxyethyl]-2-(hydroxymethyl)phenol; sulfuric acid.

Structural Formula:



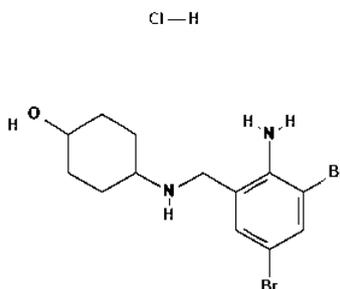
### **Ambroxol Hydrochloride**

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: C<sub>13</sub>H<sub>19</sub>Br<sub>2</sub>ClN<sub>2</sub>O.

Chemical Name: 4-[(2-amino-3,5-dibromophenyl)methylamino]cyclohexan-1-ol; hydrochloride.  
Structural Formula:



### **Guaiphenesin**

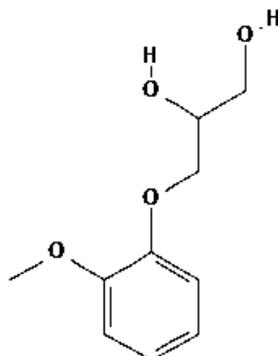
Guaiphenesin, also called as guaifenesin or glyceryl guaiacolate, is an expectorant which promotes or facilitates the removal of secretions from the respiratory tract. Guaiphenesin is a white or slightly gray crystalline substance with a slightly bitter aromatic taste.

Molecular Weight: 198.21 g/mol.

Molecular Formula: C<sub>10</sub>H<sub>14</sub>O<sub>4</sub>.

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

Structural Formula:



Inactive ingredients : Sodium Citrate, Sodium Chloride, Sucralose, Neotame, Menthol, Tartrazine, Sodium Benzoate, Hydroxyethyl Cellulose, Propylene Glycol, Mixed Fruit Flavour, Pineapple Flavour, Citric Acid Monohydrate & Purified Water.

## **8. Pharmaceutical Particulars**

### **8.1 Incompatibilities**

None known.

### **8.2 Shelf-life**

24 Months

### **8.3Packaging Information**

100 ml bottle with a 10 ml measuring cup.

### **8.4Storage and Handling Instructions**

Store below 25°C. Protect from light.

Keep out of reach of children.

## **9. Patient Counseling Information**

### Instructions to Patients

- Instruct patients to ensure the prescribed dose of TUSQ-LS Liquid is taken as directed. Patients should not exceed the recommended dose or duration of treatment.
- Pregnant women 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 nursing mothers not to take this medicine while breastfeeding to their neonate/infant 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.
- Avoid this medicine in patients with significant renal and/or liver dysfunction.
- 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**

### **Tirupati Medicare Ltd.**

Nahan Road, Paonta Sahib, Dist. Sirmour, Himachal Pradesh – 173025, India.

## **11. Details of Permission or License Number with Date**

Mfg. Lic. No. : MNB/07/552, Date of FDA Product Permission: 15/06/2017

## **12. Date of Revision**

March 2021.



Marketed by:

**BLUE CROSS LABORATORIES PVT LTD.**

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