SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT: Terbutaline Sulphate, Bromhexine Hydrochloride & Guaifenesin Syrup.

Brand Name: TusQ – X Liquid

Strength: Terbutaline Sulphate 1.25 mg, Bromhexine Hydrochloride 4 mg & Guaifenesin 50 mg per 5 ml

Pharmaceutical form: Oral Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative declaration:

Each 5 ml. contains:

Terbutaline Sulphate BP..... 1.25 mg.

Bromhexine Hydrochloride BP..... 4 mg.

Guaifenesin USP..... 50 mg

Flavoured Mentholated Base..... q.s.

Approved Colour: Brilliant Blue FCF &

Tartrazine For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Green coloured clear liquid with pleasant flavour.

Packed in amber colour PET bottle having golden colour ROPP cap with Blue Cross logo on top and 'BLUE CROSS' text printed on Blue coloured band in reverse Golden colour with EP wad, fitted with 10 ml transparent measuring cup with measuring marks 2.5 ml in Green, 5.0 ml in Blue, 7.5 ml in Yellow & 10.0 ml in Red colour and Blue Cross logo embossed on the top of the cup. 1 bottle packed in a printed carton along with pack insert.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

TusQ - X Liquid is indicated for symptomatic treatment of productive cough associated with respiratory disorders such as lower respiratory tract infections, COPD, asthma, etc.

4.2 Posology and method of administration:

For oral administration.

1. **Dosage Recommendation in Children:**

- **2 to 6 years:** 2.5 ml to be administered 3 times daily.
- **6 to 12 years:** 5 ml to be administered 3 times daily.

2. **Dosage Recommendation in Adults and Children above 12 Years of Age:**

10 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.

Special populations

Elderly population: 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.

Pediatric population: 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

pediatric patients below 2 years of age. For dosage in children above 2 years of age, please refer 'Posology and Method of Administration' section.

4.3 Contraindications:

TusQ - X Liquid is contraindicated in the following:

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

4.4 Special warnings and precautions for use:

Terbutaline Sulphate: As for all β2 agonists caution should be observed in patients with thyrotoxicosis. Cardiovascular effects may be seen with sympathomimetic drugs. Due to the positive inotropic effect of β2-agonists, these drugs should not be used in patients with hypertrophic cardiomyopathy. Patients with underlying severe heart disease (e.g. ischaemic 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 hyperglycaemic effects of β2- agonists, additional blood glucose control is recommended initially for diabetic patients. Potentially serious hypokalaemia may result from β2-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia.

Bromhexine Hydrochloride: Mucolytics such as bromhexine may disrupt the gastric mucosal barrier, thus, bromhexine should be used with caution in patients with a history of gastric ulceration.

Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

Guaifenesin: 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 Interaction with other medicinal products and other forms of interaction: 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.

Bromhexine Hydrochloride

Bromhexine may increase the concentration of concurrently administered antibiotics in bronchial secretions. No clinically relevant interactions with other medications have been reported.

Guaifenesin

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 Fertility, Pregnancy and Lactation: Pregnancy

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.

There is no data on the use of bromhexine in pregnant women. Bromhexine crosses the placental barrier. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Clinical experience to date has shown no evidence of harmful effects on the foetus during pregnancy. Nonetheless, the usual precautions regarding the use of drugs during pregnancy should be observed. Especially during the first trimester, the use of bromhexine 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.

Breast-feeding

Terbutaline is excreted in breast milk. However its adverse effects on the infant is unlikely. Bromhexine is excreted in breast milk. Although unfavourable effects on breastfed infants would not be expected. 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.

4.7 Effects 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 Bromhexine 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.

4.8 Undesirable 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 other adverse effects reported 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.

Bromhexine Hydrochloride: Dermatologic Effects - skin rash, urticaria; Gastrointestinal Effects - nausea, epigastric pain, vomiting, and diarrhoea; Hepatic Effects - transient elevations in serum aminotransferase levels; Neurologic Effects - dizziness and headache; Renal Effects - nocturnal enuresis.

Guaifenesin: 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose:

Terbutaline Sulphate

Possible symptoms and signs include headache, anxiety, tremor, nausea, tonic spasm, palpitations, tachycardia, and arrhythmia. A fall in blood pressure sometimes occurs. Laboratory findings; hypokalaemia, hyperglycaemia and lactic acidosis sometimes occur.

Treatment includes Gastric lavage, administration of activated charcoal. Determination of acid-base balance, blood sugar and electrolytes, particularly serum potassium levels. Monitoring of the heart rate and rhythm and blood pressure. Metabolic changes should be corrected. A cardioselective β-blocker (e.g. metoprolol) is recommended for the treatment of arrhythmias causing haemodynamic deterioration. The β-blocker should be used with care because of the possibility of inducing bronchoconstriction: use with caution in patients with a history of bronchospasm. If the β2-mediated reduction in the peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

Bromhexine Hydrochloride

No specific overdose symptoms have been reported in man to date. If they occur, supportive and symptomatic treatment should be provided.

Guaifenesin

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 Pharmacodynamic properties: 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.

Bromhexine Hydrochloride: Bromhexine is a mucolytic used in the treatment of respiratory disorders with associated productive cough. Bromhexine acts on the mucus at the formative stages in the glands, within the mucus-secreting cells. Bromhexine disrupts the structure of acid mucopolysaccharide fibers in mucoid sputum and produces less viscous mucus, which is easier to expectorate.

Guaifenesin:

Guaifenesin is thought to exert its pharmacological 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 stimulating

vagal nerve endings in bronchial secretory glands and stimulating certain centers in the brain, which in turn enhance respiratory fluid flow.

5.2 Pharmacokinetic properties:

Terbutaline Sulphate

Fasting bioavailability after oral doses is reported to be about 14 to 15% and is reduced by food. 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.

Bromhexine Hydrochloride

Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract; peak plasma concentrations occur after about 1 hour. Bromhexine undergoes extensive first-pass metabolism in the liver: its oral bioavailability is stated to be only about 20%. It is widely distributed to body tissues. About 85 to 90% of a dose is excreted in the urine mainly as metabolites. Bromhexine is highly bound to plasma proteins. It has a terminal elimination half-life of 13 to 40 hours.

Guaifenesin

Guaifenesin 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.

5.3 Preclinical safety data: 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. No carcinogenic, teratogenic and mutagenic effects were not observed with Terbutaline.

Bromhexine Hydrochloride: No genotoxicity and carcinogenicity data available

Guaiphenesin: There is no relevant information available.

6. Pharmaceutical particulars

6.1 List of excipients:

Sodium Benzoate, Xanthan Gum, Glycerol, Propylene Glycol, Sucralose, Sodium Citrate, Citric Acid Monohydrate, Flavour Mixed Fruit, Flavour Liquorice, Colour Tartrazine, Colour Brilliant Blue, Levomenthol & Purified Water.

6.2 Incompatibilities:

None Known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light.

6.5 Nature and contents of container:

Pet bottle Amber 100 ml	Sealed with 25 mm ROPP cap with EP WAD and 10 ml measuring cup.
Shipper Box	72 Bottles
Shipper Packing	72 labeled bottles in a carton with leaflet to be packed in (8 x 9) style. Packed with BOPP Tape having 'Blue Cross' Logo with "H" type packing on bottom and topside.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing Authorisation Holder and Manufacturing Site Addresses

Blue Cross Laboratories Pvt Ltd.

A - 12, MIDC, Ambad, Nashik – 422 010, Maharashtra, India.

8 Marketing Authorisation Number

13059

9. Date of First Registration/Renewal of the Registration

Date of last renewal of registration - 01/01/2026

10. Date of Revision of the Text

March 2026.