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

Dextromethorphan Hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Dispersible Tablets

(Brand Name: TUSQ®-Dx DT)

2. Qualitative and Quantitative Composition

Each Dispersible Uncoated Tablet Contains:
Dextromethorphan Hydrobromide IP ……..…10 mg.
Chlorpheniramine Maleate IP ……...… 2 mg.
Phenylephrine Hydrochloride IP ……...… 5 mg.
Excipients …… q.s.
Colour: Tartrazine.

3. Dosage Form and Strength

Dosage Form: Dispersible tablets.
Dosage Strength: Dextromethorphan hydrobromide 10 mg, chlorpheniramine maleate 2 mg, phenylephrine hydrochloride 5 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

TUSQ-Dx Dispersible Tablets are indicated for symptomatic relief of dry cough due to upper respiratory tract infections (URTIs) or upper respiratory allergies.

4.2Posology and Method of Administration

For oral administration.

- **Adults and adolescents:** 1 to 2 tablets to be administered 3 to 4 times daily.
- **Children between 6 to 12 years:** 1 tablet to be administered 3 to 4 times daily.

In adults, maximum recommended daily dose of dextromethorphan hydrobromide is 120 mg, chlorpheniramine maleate 24 mg, and phenylephrine hydrochloride 60 mg. Maximum recommended daily dose of individual components should not be exceeded.
Tablets are sweetened and flavoured. The tablets should be dispersed in water immediately before use.
Or, as prescribed by the physician.

4.3Contraindications

TUSQ-Dx Dispersible Tablets are contraindicated for use in the following:

- Hypersensitivity to dextromethorphan, chlorpheniramine maleate, phenylephrine or to any component of this formulation.
- In patients who have been treated with monoamine oxidase (MAO) inhibitors within the last 14 days.
- In patients who are currently receiving other sympathomimetic drugs.
- Cardiovascular disorders.
- In patients with hypertension, peripheral vascular insufficiency, and hyperthyroidism.
- In patients with glaucoma or urinary retention.
- Pheochromocytoma.
- Dextromethorphan-containing preparations should not be given to subjects having or at risk of developing respiratory failure.
- In patients taking serotonin reuptake inhibitors (SSRIs).

4.4Special Warnings and Precautions for Use

Dextromethorphan Hydrobromide

Administration of dextromethorphan may be accompanied by histamine release and should be used with caution in children with atopic dermatitis.

Use of dextromethorphan with alcohol or other central nervous system (CNS) depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

Dextromethorphan is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population is poor metabolisers of CYP2D6. Poor metabolisers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of dextromethorphan. Caution should therefore be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take dextromethorphan-containing preparations.

Cases of drug abuse have been reported with higher doses of dextromethorphan. Thus, caution is recommended in patients with a history of drug abuse or psychoactive substances.

Chlorpheniramine Maleate

Chlorpheniramine maleate may cause drowsiness and may have additive CNS effects with alcohol or other CNS depressants (e.g., hypnotics, sedatives, tranquilizers).

Antihistamines should be used with caution in patients with peptic ulcer, pyloroduodenal obstruction, and urinary bladder obstruction due to symptomatic prostatic hypertrophy and narrowing of the bladder neck.

Chlorpheniramine, in common with other drugs having anticholinergic effects, should be used with caution in the following conditions: Epilepsy; raised intra-ocular pressure including glaucoma; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment. Children and the elderly are more likely to experience the

neurological anticholinergic effects and paradoxical excitation (e.g., increased energy, restlessness, nervousness).
Chlorpheniramine should not be used with other antihistamine-containing products.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take chlorpheniramine-containing preparations.

Phenylephrine Hydrochloride
Sympathomimetic amines should be used with caution in patients with hypertension, diabetes mellitus, heart disease (angina), peripheral vascular disease, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy.
Phenylephrine should not be used with other sympathomimetics (such as decongestants, appetite suppressants, and amphetamine-like psychostimulants).
Sympathomimetic-containing products may act as cerebral stimulants giving rise to insomnia, nervousness, hyperpyrexia, tremor, and epileptiform convulsions.

4.5Drug Interactions

Dextromethorphan Hydrobromide
MAO Inhibitors: Patients may develop hyperpyrexia, hypotension, nausea, myoclonic leg jerks, and coma following co-administration of MAO inhibitors and dextromethorphan. Thus, concomitant administration of dextromethorphan and MAO inhibitors should be avoided.
CYP2D6 Inhibitors (Fluoxetine, Paroxetine, Quinidine, Terbinafine): Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient's risk for toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhoea, and respiratory depression) and development of serotonin syndrome. In concomitant use with quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold, which has increased the CNS adverse effects of the agent. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.
Alcohol, Antihistamines, Psychotropics, and Other CNS Depressant Drugs: Dextromethorphan might exhibit additive CNS depressant effects when co-administered with these drugs.

Chlorpheniramine Maleate
Alcohol, Hypnotics, Anxiolytics, Sedatives, Opioid Analgesics, and Neuroleptics: Concurrent use of chlorpheniramine maleate with any of these drugs may enhance the sedative effect.
Phenytoin: Chlorpheniramine maleate inhibits phenytoin metabolism and can lead to phenytoin toxicity.
MAO Inhibitors and Tricyclic Antidepressants: The antimuscarinic effects of chlorpheniramine are enhanced by other antimuscarinic drugs and both antimuscarinic and

sedative effects are enhanced by MAO inhibitors (concurrent therapy is contraindicated) and tricyclic antidepressants.

Phenylephrine Hydrochloride

MAO Inhibitors: Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and MAO inhibitors, thus concomitant use is contraindicated.

Sympathomimetic Amines: Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.

Beta-Blockers and Other Antihypertensives (Including Debrisoquine, Guanethidine, Reserpine, and Methyldopa): Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.

Tricyclic Antidepressants (Amitriptyline): Concomitant use of phenylephrine with amitriptyline may increase the risk of cardiovascular side effects.

Ergot Alkaloids (Ergotamine and Methylsergide): Concomitant use of phenylephrine with these drugs increases risk of ergotism.

Digoxin and Cardiac Glycosides: Co-administration of phenylephrine with these drugs increases risk of irregular heartbeat or heart attack.

4.6Use in Special Populations

Pregnant Women

Pregnancy Category: Dextromethorphan Hydrobromide - C, Chlorpheniramine Maleate - B, Phenylephrine Hydrochloride - C. It is not known whether components of TUSQ-Dx Dispersible Tablets (dextromethorphan hydrobromide, chlorpheniramine maleate, and phenylephrine hydrochloride) can cause fetal harm when administered to a pregnant woman. Use of chlorpheniramine during the third trimester of pregnancy may result in reactions in the newborn or premature neonates. Thus, TUSQ-Dx Dispersible Tablet should not be used during pregnancy unless considered mandatory by a physician.

Lactating Women

It is not known whether dextromethorphan or its metabolites are excreted in human milk. Phenylephrine is excreted in breast milk, but not in a clinically significant amount. Chlorpheniramine maleate may inhibit lactation and may be secreted in breast milk. Because of higher risk of intolerance of antihistamines in newborns and infants, TUSQ-Dx Dispersible Tablets should not be administered to a nursing mother.

Paediatric Patients

TUSQ-Dx Dispersible Tablets are not intended for use in children below 6 years of age as there is no feasibility of dosage adjustment in this population. It is advised that children between 2 to 6 years of age should use the liquid formulation of this combination.

Geriatric Patients

Usually, no dose adjustment is considered necessary in elderly patients with normal renal and hepatic function. 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

Dextromethorphan, chlorpheniramine maleate, and phenylephrine are primarily excreted by the kidney. Impaired renal function could potentially lead to the risk of decreased clearance and thereby increased plasma levels of these drugs. TUSQ-Dx Dispersible Tablets should be used with caution in patients with severe impairment of renal function, and patients should be monitored closely for signs of toxicity.

Hepatic Impairment Patients

Due to the extensive hepatic metabolism of dextromethorphan, chlorpheniramine maleate, and phenylephrine caution should be exercised in the presence of moderate to severe hepatic impairment.

4.7Effect on Ability to Drive and Use Machines

Phenylephrine has no adverse effects on the patient’s ability to drive and to use machines. Dextromethorphan may impair cognitive function and can affect a patient's ability to drive safely. Also, the anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision, and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery. If affected by dizziness, patients should not drive a vehicle or operate machinery.

4.8Undesirable Effects

The most common adverse effects associated with TUSQ-Dx Dispersible Tablets include drowsiness, sedation, decreased mental alertness, dryness of mucous membranes, dry mouth, and gastrointestinal disturbances. Serious side effects with oral antitussives, antihistamines, and sympathomimetics have been rare.

Other adverse events that may occur with this formulation include:

- **Dermatologic:** Urticaria, drug rash, photosensitivity, allergic reactions, skin rashes including exfoliative dermatitis, pruritus, tingling, and coolness of the skin.
- **Gastrointestinal:** Epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation.
- **Cardiovascular:** Hypotension, hypertension, cardiac arrhythmias (tachycardia or reflex bradycardia), chest pain, palpitations.
- **Central Nervous System:** Disturbed coordination, extrapyramidal effects, decreased mental/physical ability, tremor, irritability, insomnia, lassitude, visual disturbances, blurred vision, weakness, nervousness, convulsion, headache, euphoria, and dysphoria. Paradoxical CNS stimulation may occur especially in children or after high doses of chlorpheniramine maleate.
- **Genitourinary:** Urinary frequency, difficult urination, urinary retention.

- **Respiratory:** Tightness of the chest and wheezing, shortness of breath.
- **Hematologic:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
- **Other:** Sweating, liver dysfunction, including hepatitis and jaundice, myalgia, paraesthesia, tinnitus.

4.9Overdose

Dextromethorphan Hydrobromide

Symptoms: Overdose symptoms include nausea and vomiting, CNS depression, dizziness, dysarthria (slurred speech), nystagmus, somnolence/drowsiness, excitation, mental confusion, psychosis, and respiratory depression.

Management: Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use. Naloxone has been used successfully as a specific antagonist to dextromethorphan toxicity in children.

Chlorpheniramine Maleate

Symptoms: The estimated lethal dose of chlorpheniramine is 25 to 50 mg/kg body weight. Overdose with chlorpheniramine is associated with antimuscarinic, extrapyramidal, gastrointestinal, and CNS effects. In children, CNS stimulation predominates over CNS depression, causing ataxia, excitement, tremors, psychosis, hallucinations, and convulsions. Hyperpyrexia may also occur. Other symptoms of overdose in children include dilated pupils, dry mouth, facial flushing. In adults, CNS depression is more common with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse including arrhythmias.

Treatment: In severe overdose the stomach should be emptied. If overdose is by the oral route, treatment with activated charcoal should be considered (treatment is most effective if given within an hour of ingestion). Convulsions may be controlled with intravenous diazepam or phenytoin, although it has been suggested that CNS depressants should be avoided. Other treatment is supportive and symptomatic and may include artificial respiration, external cooling for hyperpyrexia, and intravenous fluids. Vasopressors such as noradrenaline or phenylephrine may be used to counteract hypotension. Forced diuresis, peritoneal dialysis or haemodialysis appear to be of limited benefit. Haemoperfusion may be used in severe cases.

Phenylephrine Hydrochloride

Symptoms: Overdose symptoms may include hypertension and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures, and arrhythmias may occur.

Treatment: Treatment measures include early gastric lavage and symptomatic and supportive measures. The hypertensive effects may be treated with an α-receptor blocking agent (such as phentolamine mesylate, 6 to 10 mg) given intravenously, and the bradycardia treated with atropine, preferably only after the pressure has been controlled.

5. Pharmacological Properties

5.1 Mechanism of Action

Dextromethorphan Hydrobromide - Cough Suppressant/Antitussive.

Dextromethorphan produces antitussive effect by acting on the cough center which is located in the medulla oblongata part of the brain. Dextromethorphan crosses the blood-brain-barrier and activates sigma opioid receptors on the cough center in the CNS, thereby suppressing the cough reflex. Dextromethorphan raises the threshold for the cough reflex, thereby produces cough suppressant effect.

Chlorpheniramine Maleate – Antihistamine.

Chlorpheniramine maleate is H_1 receptor antagonist (antihistamine effect). Chlorpheniramine maleate diminishes or abolishes the actions of histamine in the body by competitive (reversible) blockade of histamine H_1 receptor sites on tissues. Chlorpheniramine maleate prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Phenylephrine Hydrochloride - Sympathomimetic Nasal Decongestant.

Phenylephrine is a nasal decongestant with a potent postsynaptic α-receptor agonist activity. Dilated blood vessels can cause nasal blocks or stuffy nose. Phenylephrine shrinks blood vessels in the nasal passages and thus, reduces nasal congestion. A direct action at the receptors accounts for the greater part of its effects, whereas only a small part of effect is due to its ability to release norepinephrine.

Sympathomimetic amines, such as phenylephrine, act on α-adrenergic receptors of the respiratory tract to produce vasoconstriction effect. This result in temporarily reduction of swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses. In addition to reducing mucosal lining swelling, phenylephrine also suppresses the production of mucous, therefore preventing a buildup of fluid within the nasal cavities.

5.2Pharmacodynamic Properties

Dextromethorphan Hydrobromide

Dextromethorphan is a non-opioid antitussive (cough suppressant) drug. Dextromethorphan is the dextrorotatory isomer of 3-methoxy-N-methyl-morphinan. It is a synthetic morphine derivative that, in contrast to its levorotatory isomer, has no significant analgesic, respiratory depressant or physical dependency properties at recommended doses. It is reported that dextromethorphan has similar efficacy to codeine in depressing cough reflex. In therapeutic dosage dextromethorphan does not inhibit ciliary activity.

Chlorpheniramine Maleate

Chlorpheniramine maleate produces antihistamine effect by blocking H_1 receptor. Chlorpheniramine maleate also possesses anticholinergic activity.

Phenylephrine Hydrochloride

Phenylephrine is an orally active sympathomimetic amine and exerts a decongestant action on the nasal mucosa.

5.3Pharmacokinetic Properties

Dextromethorphan Hydrobromide

Absorption: Dextromethorphan is rapidly absorbed from the gastrointestinal tract with peak plasma concentrations reached in approximately 2 to 2.5 hours. The low plasma levels of dextromethorphan suggest low oral bioavailability secondary to extensive first-pass (pre-systemic) metabolism in the liver. The maximum clinical effects occur 5 to 6 hours after ingestion of dextromethorphan.

Distribution: Dextromethorphan is widely distributed in the human body. Dextromethorphan and its active metabolite, dextrorphan, are actively taken up and concentrated in brain tissue.

Metabolism: Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Unmetabolised dextromethorphan, together with the three demethylated metabolites such as dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3- hydroxymorphinan, and 3-methoxymorphinan have been identified as conjugated products in the urine. Dextrorphan, which also has antitussive action, is the main metabolite. In some individuals metabolism proceeds more slowly and unchanged dextromethorphan predominates in the blood and urine.

Excretion: Dextromethorphan is primarily excreted via the kidney as unchanged parent drug and its active metabolite, dextrorphan. Dextrorphan and 3-hydroxy-morphinan are further metabolised by glucuronidation and are eliminated via the kidneys. The elimination half-life of the dextromethorphan is between 1.4 to 3.9 hours, while half-life of dextrorphan, the main metabolite, is between 3.4 to 5.6 hours. The half-life of dextromethorphan in poor metabolisers is extremely prolonged, in the range of 45 hours.

Chlorpheniramine Maleate

Absorption: Chlorpheniramine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours.

Distribution: The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10l/kg. About 70% of chlorpheniramine in the circulation is protein-bound.

Metabolism and Excretion: Chlorpheniramine undergoes some first pass metabolism and enterohepatic recycling. Chlorpheniramine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the faeces. The mean elimination half-life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours.

Phenylephrine Hydrochloride

Absorption: Phenylephrine hydrochloride is rapidly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by MAO in the gut and liver. As a consequence, systemic bioavailability of oral route is only about 40%. Following oral administration, peak plasma concentration is achieved in 1 to 2 hours.

Distribution: Penetration into the brain appears to be minimal.
Metabolism and Excretion: Following absorption, the drug is extensively metabolised in the liver as the sulphate conjugate. Both phenylephrine and its metabolites are excreted in the urine. The mean plasma half-life is in the range 2 to 3 hours.

6. Nonclinical Properties

6.1 Animal Toxicology

Dextromethorphan Hydrobromide

Toxicity: LD50 values reported for dextromethorphan was 210 mg/kg in mouse and 116 mg/kg in rat. Acute subcutaneous toxicity with dextromethorphan reports the LD50 value of 112 mg/kg in mouse. Acute intravenous toxicity with dextromethorphan reports the LD50 value of 16.3 mg/kg in rat.

Repeat dose toxicity studies conducted in rats for 13 weeks duration at doses up to 100 mg/kg and 27 weeks at 10 mg/kg, and of 14 weeks in dogs by oral gavage at doses up to 4 mg/kg on 5 days per week. The only effect recorded was of reduced body weight gain in the rat 13-week study at the highest dose.

Mutagenicity: Dextromethorphan hydrobromide was negative in the bacterial reverse mutation assay (Ames test). Dextromethorphan 39 mg/kg is reported to be negative in *in-vivo* mouse micronucleus test and comet assay. Dextromethorphan was reported to be negative in *in- vitro* chromosome aberration assay tested up to 200 µg/ml.

Chlorpheniramine Maleate

Toxicity: LD50 values reported for chlorpheniramine maleate by oral route in rats, mice, and guinea pigs were 118, 121, and 186 mg/kg respectively.

Chlorpheniramine maleate was administered by gavage to groups of 12 female Sprague-Dawley rats for 29 days at doses of 0, 2, 5, 10, or 25 mg/kg body weight and in feed (average daily dose, 1 mg/kg) for three successive generations to male and female Sprague-Dawley rats. No clinical, hematologic, or pathologic alterations were apparent in either study.

No compound-related effects were reported after chlorpheniramine maleate was administered by gavage to groups of 8 male and 8 female rats 5 days per week for 6 weeks at doses of 5 or 10 mg/kg per day. Similar experiments in which two rhesus monkeys were administered 20 mg/kg per day 5 days per week for 7 weeks resulted in no apparent adverse effects.

Mutagenicity: Chlorpheniramine maleate was not mutagenic to *Salmonella typhimurium* strains TA98, TA100, TA1535, or TA1537 in the presence or absence of S9 metabolic activation systems prepared from the livers of Aroclor 1254-treated male Sprague-Dawley rats or male Syrian hamsters.

Carcinogenicity: A 2-year oncogenicity study of chlorpheniramine maleate was conducted in which groups of 50 male and 50 female CD albino rats were fed diets containing SCH 190 (Chlor-trimeton') for 103 weeks. The doses (approximately 2, 10, or 20 mg/kg per day) were formulated based on group mean values for body weight and feed consumption. There were no reported increases in the incidences of neoplastic lesions attributed to dosing with chlorpheniramine maleate.

Phenylephrine Hydrochloride

Toxicity: LD50 values for phenylephrine have been determined in several species by various routes of administration. In Wistar rats, the LD50 value by intraperitoneal injection was 17 mg/kg and by subcutaneous injection was 33 mg/kg. The LD50 values in male Swiss mice were 89 mg/kg (intraperitoneal) and 22 mg/kg (subcutaneous). New Zealand rabbits had LD50 values of 0.5 mg/kg (intravenous), 7.2 mg/kg (intramuscular), and 22 mg/kg (subcutaneous).

Mutagenicity: Phenylephrine hydrochloride was not mutagenic in four tester strains of *Salmonella typhimurium* (TA100, TA1535, TA1537, and TA98) in the presence or absence of Aroclor 1254-induced male Sprague-Dawley rat or male Syrian hamster liver S9.

Carcinogenicity: In the mouse study, the mean daily dose (males and females) in the low dose animals was 133 mg/kg and in the high dose animals 270 mg/kg. The study demonstrated no evidence of carcinogenicity in rats and mice under the testing conditions employed.

7. Description

TUSQ-Dx Dispersible Tablets are Yellow coloured, circular, biconvex, uncoated tablet with $^{TusQ\ Dx}$ engraved on one side and plain on other side.

Each dispersible tablet of TUSQ-Dx contains 10 mg of dextromethorphan hydrobromide, 2 mg of chlorpheniramine maleate, and 5 mg of phenylephrine hydrochloride for oral administration.

Dextromethorphan Hydrobromide

Dextromethorphan is a non-opioid antitussive drug. Dextromethorphan Hydrobromide is the hydrobromide salt form of dextromethorphan, a synthetic, methylated dextrorotary analogue of levorphanol, a substance related to codeine and a non-opioid derivate of morphine.

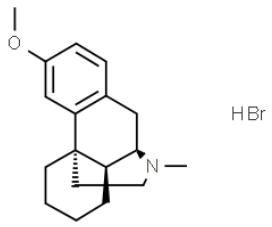
Dextromethorphan hydrobromide is a white to slightly yellow crystalline powder, odourlss, and insoluble in water.

Molecular Weight: 271.4 g/mol.

Molecular Formula: C18H26BrNO.

Chemical Name: Morphinan, 3-methoxy-17-methyl-, (9α, 13α, 14α), hydrobromide.

Structural Formula:

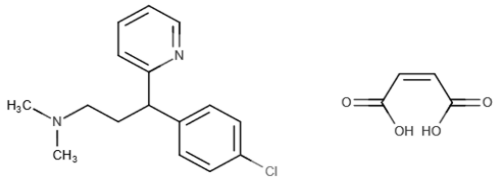


Chlorpheniramine Maleate

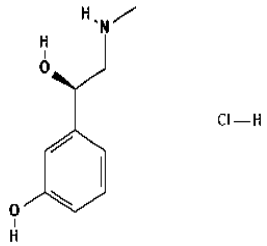
Chlorpheniramine maleate is H_1 receptor antagonist. Chlorpheniramine maleate appears as odorless white crystalline solid or white powder with a bitter taste.

Molecular Weight: 390.9 g/mol.

Molecular Formula: C20H23ClN2O4.
Chemical Name: (2Z)-but-2-enedioic acid; [3-(4-chlorophenyl)-3-(pyridin-2-yl)propyl] dimethylamine
Structural Formula:



Phenylephrine Hydrochloride
Phenylephrine is a nasal decongestant with a potent postsynaptic α-receptor agonist activity. Phenylephrine hydrochloride is an odorless white microcrystalline powder with a bitter taste.
Molecular Weight: 203.66 g/mol.
Molecular Formula: C9H14ClNO2.
Chemical Name: 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol; hydrochloride.
Structural Formula:



Inactive ingredients: Microcrystalline Cellulose, Starch, Dibasic Calcium Phosphate, Sucralose, Colour Tartrazine, Citric Acid Anhydrous, Colloidal Silicon Dioxide, Flavour Trusil Lemon, Masking Flavour, Croscarmellose Sodium, Mono-ammonium Glycyrrhizinate & Magnesium Stearate.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 months.

8.3Packaging Information

Strip of 10 tablets.

8.4Storage and Handling Instructions

Store protected from light and moisture, at a temperature not exceeding 30°C.
Keep out of reach of children.

9. Patient Counseling Information

Instructions to Patients

- Instruct patients to ensure the prescribed doses of TUSQ-Dx Dispersible Tablets are taken as directed. Patients should not exceed the recommended dose or duration of treatment.
- Instruct patients not to take this product during pregnancy and lactation unless advised by healthcare professionals.
- Avoid use of this medicine in children below 6 years of age.
- Not to use with other cough and cold relief products (prescription or over-the- counter - OTC) having similar type of ingredients. If users are sure about presence of such ingredients in their medicine, consult a doctor or pharmacist.
- Patients should remove tablets from its original packing just before its use and then disperse the tablet in water and consume.

10. Details of Manufacturer

Blue Cross Laboratories Pvt Ltd.
L – 17, Verna Industrial Estate, Verna, Goa – 403722.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 271, Date of FDA Product Permission: 11/08/2020

12. Date of Revision

March 2021.

MADE IN INDIA BY
BLUE CROSS LABORATORIES PVT LTD.
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