PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE- promethazine hydrochloride and dextromethorphan hydrobromide solution
ANI Pharmaceuticals, Inc.

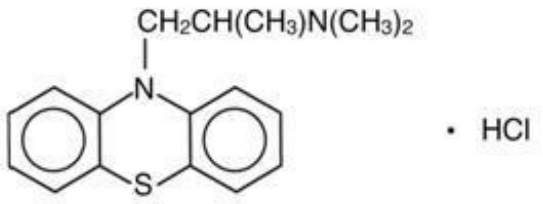
Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution
Rx Only

DESCRIPTION

Each 5 mL (teaspoon) of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution contains 6.25 mg promethazine hydrochloride USP and 15 mg dextromethorphan hydrobromide USP in a flavored syrup base with a pH between 4.5 and 5.5. The inactive ingredients present are alcohol 7% (v/v), ascorbic acid, citric acid, black currant flavor, D&C Yellow 10, edetate disodium, FD&C Yellow 6, glycerin, L-Menthol, sodium benzoate, sodium citrate, sodium propionate, saccharin sodium, sucrose, and water.

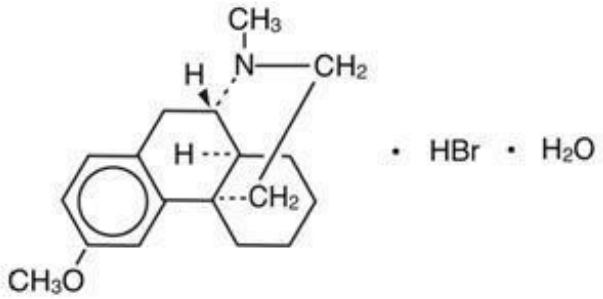
Promethazine hydrochloride USP is a racemic compound; the empirical formula is $C_{17}H_{20}N_2S$•HCl and its molecular weight is 320.88.

Promethazine hydrochloride USP, a phenothiazine derivative, is chemically designated as 10*H*-Phenothiazine-10-ethanamine, *N*,*N*, α-trimethyl-, monohydrochloride, (+)- with the following structural formula:



Promethazine hydrochloride USP occurs as a white to faint yellow, practically odorless, crystalline powder which slowly oxidizes and turns blue on prolonged exposure to air. It is freely soluble in water and soluble in alcohol.

Dextromethorphan hydrobromide USP is a salt of the methyl ether of the dextrorotatory isomer of levorphanol, a narcotic analgesic. It is chemically designated as 3-methoxy-17-methyl-9α, 13α, 14α–morphinan hydrobromide monohydrate with the following structural formula:



Dextromethorphan hydrobromide monohydrate occurs as white crystals, is sparingly soluble in water, and is freely soluble in alcohol. The empirical formula is $C_{18}H_{25}NO \cdot HBr \cdot H_2O$, and the molecular weight of the monohydrate is 370.33. Dextromethorphan hydrobromide monohydrate is dextrorotatory with a specific rotation of +27.6 degrees in water (20 degrees C, sodium D-line).

CLINICAL PHARMACOLOGY

PROMETHAZINE

Promethazine is a phenothiazine derivative which differs structurally from the antipsychotic phenothiazines by the presence of a branched side chain and no ring substitution. It is thought that this configuration is responsible for its relative lack (1/10 that of chlorpromazine) of dopamine antagonist properties.

Promethazine is an H_1 receptor blocking agent. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic effects.

Promethazine is well absorbed from the gastrointestinal tract. Clinical effects are apparent within 20 minutes after oral administration and generally last four to six hours, although they may persist as long as 12 hours.

Promethazine is metabolized by the liver to a variety of compounds; the sulfoxides of promethazine and N-demethylpromethazine are the predominant metabolites appearing in the urine.

DEXTROMETHORPHAN

Dextromethorphan is an antitussive agent and, unlike the isomeric levorphanol, it has no analgesic or addictive properties.

Dextromethorphan acts centrally and elevates the threshold for coughing. It is about equal to codeine in depressing the cough reflex. In therapeutic dosage dextromethorphan does not inhibit ciliary activity.

Dextromethorphan is rapidly absorbed from the gastrointestinal tract and exerts its effect in 15 to 30 minutes. The duration of action after oral administration is approximately three to six hours.

Dextromethorphan is metabolized primarily by liver enzymes undergoing O-demethylation, N-demethylation, and partial conjugation with glucuronic acid and sulfate. In humans, (+)-3-hydroxy-N-methylmorphinan, (+)-3-hydroxymorphinan, and traces of unmetabolized drug were found in urine after oral administration.

INDICATIONS AND USAGE

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is indicated for the temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold.

CONTRAINDICATIONS

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is contraindicated for use in pediatric patients less than two years of age.

Promethazine is contraindicated in comatose states, and in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines.

Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms, including asthma.

Dextromethorphan should not be used in patients receiving a monoamine oxidase inhibitor (see **PRECAUTIONS – Drug Interactions**).

WARNINGS

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

Postmarketing cases of respiratory depression, including fatalities, have been reported with use of promethazine in pediatric patients less than 2 years of age. A wide range of weight-based doses of promethazine have resulted in respiratory depression in these patients.

Caution should be exercised when administering promethazine to pediatric patients 2 years of age and older. It is recommended that the lowest effective dose of promethazine be used in pediatric patients 2 years of age and older and concomitant administration of other drugs with respiratory depressant effects be avoided.

PROMETHAZINE

CNS Depression

Promethazine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. The impairment may be amplified by concomitant use of other central-

nervous-system depressants such as alcohol, sedatives/hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers; therefore such agents should either be eliminated or given in reduced dosage in the presence of promethazine (see **PRECAUTIONS – Information for Patients and Drug Interactions**).

Respiratory Depression

Promethazine may lead to potentially fatal respiratory depression.

Use of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution in patients with compromised respiratory function (e.g. COPD, sleep apnea syndrome) should be avoided.

Lower Seizure Threshold

Promethazine may lower seizure threshold. It should be used with caution in persons with seizure disorders or in persons who are using concomitant medications, such as narcotics or local anesthetics, which may also affect seizure threshold.

Bone-Marrow Depression

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be used with caution in patients with bone-marrow depression. Leukopenia and agranulocytosis have been reported, usually when promethazine has been used in association with other known marrow-toxic agents.

Neuroleptic Malignant Syndrome

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with promethazine alone or in combination with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmias).

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g. pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system (CNS) pathology.

The management of NMS should include 1) immediate discontinuation of promethazine, antipsychotic drugs, if any, and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS.

Since recurrences of NMS have been reported with phenothiazines, the reintroduction of promethazine should be carefully considered.

Use in Pediatric Patients

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is contraindicated for use in pediatric patients less than two years of age.

Caution should be exercised when administering Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution to pediatric patients 2 years of age and older because of the potential for fatal respiratory depression. Respiratory depression and apnea, sometimes associated with death, are strongly associated with promethazine products and are not directly related to individualized weight-based dosing, which might otherwise permit safe administration. Concomitant administration of promethazine products with other respiratory depressants has an association with respiratory depression, and sometimes death, in pediatric patients.

Antiemetics are not recommended for treatment of uncomplicated vomiting in pediatric patients, and their use should be limited to prolonged vomiting of known etiology. The extrapyramidal symptoms which can occur secondary to Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution administration may be confused with the CNS signs of undiagnosed primary disease, e.g., encephalopathy or Reye's syndrome. The use of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be avoided in pediatric patients whose signs and symptoms may suggest Reye's syndrome or other hepatic diseases.

Excessively large dosages of antihistamines, including promethazine, in pediatric patients may cause sudden death (see **OVERDOSAGE**). Hallucinations and convulsions have occurred with therapeutic doses and overdoses of Promethazine in pediatric patients.

In pediatric patients who are acutely ill associated with dehydration, there is an increased susceptibility to dystonias with the use of promethazine.

Other Considerations

Administration of promethazine has been associated with reported cholestatic jaundice.

DEXTROMETHORPHAN

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

PRECAUTIONS

General

Drugs having anticholinergic properties should be used with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction and bladder-neck obstruction. Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be used cautiously in persons with cardiovascular disease or with impairment of liver function.

Dextromethorphan should be used with caution in sedated patients, in the debilitated, and in patients confined to the supine position.

Information for Patients

Patients should be advised to measure Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution with an accurate measuring device. A household teaspoon is not an accurate measuring device and could lead to overdosage, especially when a half a teaspoon is measured. A pharmacist can recommend an appropriate measuring device and can provide instructions for measuring the correct dose.

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution may cause marked drowsiness or impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. Ambulatory patients should be told to avoid engaging in such activities until it is known that they do not become drowsy or dizzy from promethazine and dextromethorphan therapy. Pediatric patients should be supervised to avoid potential harm in bike riding or in other hazardous activities.

The concomitant use of alcohol or other central-nervous-system depressants, such as sedatives/hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers, may enhance impairment (see **WARNINGS – CNS Depression and PRECAUTIONS – Drug Interactions**).

Patients should be advised to report any involuntary muscle movements.

Avoid prolonged exposure to the sun.

Drug Interactions

Monoamine Oxidase (MAO) Inhibitors – Hyperpyrexia, hypotension, and death have been reported coincident with the co-administration of monoamine oxidase (MAO) inhibitors and products containing dextromethorphan. Drug interactions, including an increased incidence of extrapyramidal effects, have been reported when some MAO inhibitors and phenothiazines are used concomitantly. Thus, concomitant administration of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution and MAO inhibitors should be avoided (see **CONTRAINDICATIONS**).

CNS Depressants – Promethazine may increase, prolong, or intensify the sedative action of other central-nervous-system depressants, such as alcohol, sedatives/hypnotics (including barbiturates), narcotics, narcotic analgesics, general anesthetics, tricyclic antidepressants, and tranquilizers; therefore, such agents should be avoided or administered in reduced dosage to patients receiving promethazine. When given concomitantly with Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution, the dose of barbiturates should be reduced by at least one-half, and the dose of narcotics should be reduced by one-quarter to one-half. Dosage must be individualized. Excessive amounts of promethazine relative to a narcotic may lead to restlessness and motor hyperactivity in the patient with pain; these symptoms usually disappear with adequate control of the pain.

Epinephrine – Because of the potential for promethazine to reverse epinephrine's vasopressor effect, epinephrine should NOT be used to treat hypotension associated with Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution overdose.

Anticholinergics – Concomitant use of other agents with anticholinergic properties

should be undertaken with caution.

Drug/Laboratory Test Interactions

The following laboratory tests may be affected in patients who are receiving therapy with promethazine:

Pregnancy Tests

Diagnostic pregnancy tests based on immunological reactions between HCG and anti-HCG may result in false-negative or false-positive interpretations.

Glucose Tolerance Test

An increase in blood glucose has been reported in patients receiving promethazine.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to assess the carcinogenic potential of promethazine or of dextromethorphan. There are no animal or human data concerning carcinogenicity, mutagenicity, or impairment of fertility with these drugs. Promethazine was nonmutagenic in the Salmonella test system of Ames.

Pregnancy

Teratogenic Effects

Teratogenic effects have not been demonstrated in rat-feeding studies at doses of 6.25 and 12.5 mg/kg of promethazine. These doses are 8.3 and 16.7 times the maximum recommended total daily dose for a 50-kg subject. Daily doses of 25 mg/kg intraperitoneally have been found to produce fetal mortality in rats.

Specific studies to test the action of promethazine on parturition, lactation, and development of the animal neonate were not done, but a general preliminary study in rats indicated no effect on these parameters. Although antihistamines, including promethazine, have been found to produce fetal mortality in rodents, the pharmacological effects of histamine in the rodent do not parallel those in man. There are no adequate and well-controlled studies of promethazine in pregnant women.

Animal reproduction studies have not been conducted with the drug combination – promethazine and dextromethorphan. It is not known whether this drug combination can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be given to a pregnant woman only if clearly needed. Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects

Promethazine administered to a pregnant woman within two weeks of delivery may inhibit platelet aggregation in the newborn.

Labor and Delivery

Limited data suggest that use of promethazine during labor and delivery does not have

an appreciable effect on the duration of labor or delivery and does not increase the risk of need for intervention in the newborn. The effect on later growth and development of the newborn is unknown. See also Nonteratogenic Effects.

Nursing Mothers

It is not known whether promethazine or dextromethorphan is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution, 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.

Pediatric Use

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is contraindicated for use in pediatric patients less than two years of age (see**WARNINGS – Boxed Warning and Use in Pediatric Patients**)**.**

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution should be used with caution in pediatric patients 2 years of age and older (see **WARNINGS – Use in Pediatric Patients**).

Geriatric Use

Clinical studies of promethazine formulations did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution and observed closely.

ADVERSE REACTIONS

PROMETHAZINE

Central Nervous System – Drowsiness is the most prominent CNS effect of this drug. Sedation, somnolence, blurred vision, dizziness; confusion, disorientation and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion; lassitude, tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsive seizures, excitation, catatonic-like states, hysteria. Hallucinations have also been reported.

Cardiovascular – Increased or decreased blood pressure, tachycardia, bradycardia, faintness.

Dermatologic – Dermatitis, photosensitivity, urticaria.

Hematologic – Leukopenia, thrombocytopenia, thrombocytopenic purpura,

agranulocytosis.

Gastrointestinal – Dry mouth, nausea, vomiting, jaundice.

Respiratory – Asthma, nasal stuffiness, respiratory depression (potentially fatal) and apnea (potentially fatal) (see **WARNINGS – Respiratory Depression**.)

Other – Angioneurotic edema. Neuroleptic malignant syndrome (potentially fatal) has also been reported (see **WARNINGS – Neuroleptic Malignant Syndrome**.)

Paradoxical Reactions

Hyperexcitability and abnormal movements have been reported in patients following a single administration of Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution. Consideration should be given to the discontinuation of promethazine Hydrochloride and to the use of other drugs if these reactions occur. Respiratory depression, nightmares, delirium, and agitated behavior have also been reported in some of these patients.

DEXTROMETHORPHAN

Dextromethorphan occasionally causes slight drowsiness, dizziness, and gastrointestinal disturbances.

To report SUSPECTED ADVERSE REACTIONS, contact ANI Pharmaceuticals, Inc. at 1-800-308-6755 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

According to the WHO Expert Committee on Drug Dependence, dextromethorphan could produce very slight psychic dependence but no physical dependence.

OVERDOSAGE

PROMETHAZINE

Signs and symptoms of overdosage with promethazine range from mild depression of the central nervous system and cardiovascular system to profound hypotension, respiratory depression, unconsciousness, and sudden death. Other reported reactions include hyperreflexia, hypertonia, ataxia, athetosis and extensor-plantar reflexes (Babinski reflex).

Stimulation may be evident, especially in children and geriatric patients. Convulsions may rarely occur. A paradoxical-type reaction has been reported in children receiving single doses of 75 mg to 125 mg orally, characterized by hyperexcitability and nightmares.

Atropine-like signs and symptoms – dry mouth, fixed, dilated pupils, flushing, as well as gastrointestinal symptoms - may occur.

DEXTROMETHORPHAN

Dextromethorphan may produce central excitement and mental confusion. Very high doses may produce respiratory depression. One case of toxic psychosis (hyperactivity, marked visual and auditory hallucinations) after ingestion of a single dose of 20 tablets (300 mg) of dextromethorphan has been reported.

Treatment

Treatment of overdosage with Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs, including respiration, pulse, blood pressure, temperature, and EKG, need to be monitored. Activated charcoal orally or by lavage may be given, or sodium or magnesium sulfate orally as a cathartic. Attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. Diazepam may be used to control convulsions. Acidosis and electrolyte losses should be corrected. The antidotal efficacy of narcotic antagonists to dextromethorphan has not been established; note that any of the depressant effects of promethazine are not reversed by naloxone. Avoid analeptics, which may cause convulsions.

The treatment of choice for resulting hypotension is administration of intravenous fluids, accompanied by repositioning if indicated. In the event that vasopressors are considered for the management of severe hypotension which does not respond to intravenous fluids and repositioning, the administration of norepinephrine or phenylephrine should be considered. EPINEPHRINE SHOULD NOT BE USED, since its use in a patient with partial adrenergic blockade may further lower the blood pressure. Extrapyramidal reactions may be treated with anticholinergic antiparkinson agents, diphenhydramine, or barbiturates. Oxygen may also be administered.

Limited experience with dialysis indicates that it is not helpful.

DOSAGE AND ADMINISTRATION

It is important that Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is measured with an accurate measuring device (see **PRECAUTIONS – Information for Patients**). A household teaspoon is not an accurate measuring device and could lead to overdosage, especially when half a teaspoon is to be measured. It is strongly recommended that an accurate measuring device be used. A pharmacist can provide an appropriate device and can provide instructions for measuring the correct dose.

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is CONTRAINDICATED for children under 2 years of age (see **WARNINGS – Boxed Warning and Use in Pediatric Patients**).

The average effective dose for adults is 5 mL (one teaspoon) every 4 to 6 hours, not to exceed 30.0 mL in 24 hours. For children 6 years to under 12 years of age, the dose is 2.5 to 5.0 mL (one-half to one teaspoon) every 4 to 6 hours, not to exceed 20.0 mL in 24 hours. For children 2 years to under 6 years of age, the dose is 1.25 to 2.5 mL (one-quarter to one-half teaspoon) every 4 to 6 hours, not to exceed 10.0 mL in 24 hours.

HOW SUPPLIED

Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution is a clear, yellow solution supplied as follows:

NDC 62559-758-04 – bottle of 4 fl. oz. (118 mL)

NDC 62559-758-16 – bottle of 16 fl. oz. (473 mL)

Keep bottles tightly closed.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Protect from light.

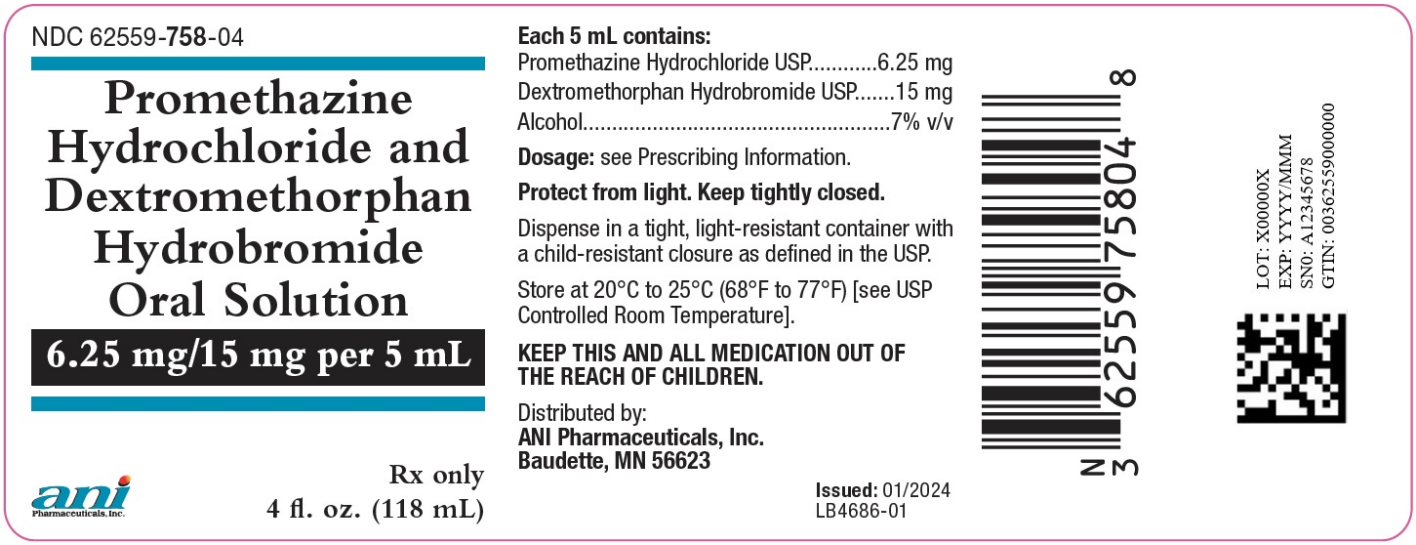
Dispense in tight, light-resistant container (USP/NF) with a child-resistant closure.

Distributed by
ANI Pharmaceuticals, Inc.
Baudette, MN 56623

Issued: 01/2024
LB4688-01

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 62559-**758**-04
Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution
6.25 mg/15 mg per 5 mL
Rx only
4 fl. oz. (118 mL)



PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE

promethazine hydrochloride and dextromethorphan hydrobromide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62559-758
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH7I1I) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	6.25 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM PROPIONATE (UNII: DK6Y9P42IN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW	**Score**	
Shape		**Size**	
Flavor	BERRY (Black Currant)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62559-758-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2024	
2	NDC:62559-758-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA011265	09/05/2024	

Labeler - ANI Pharmaceuticals, Inc. (145588013)

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