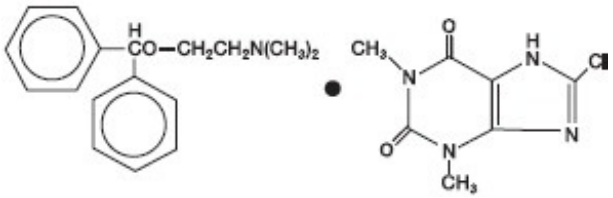
DIMENHYDRINATE - dimenhydrinate injection, solution
Fresenius Kabi USA, LLC

Dimenhydrinate Injection USP

Rx only

DESCRIPTION

Dimenhydrinate, an anti-nauseant/antiemetic, is the 8-chlorotheophylline salt of diphenhydramine. It contains not less than 53% and not more than 55.5% of diphenhydramine, and not less than 44% and not more than 47% of 8-chlorotheophylline, calculated on the dried basis. Chemically, it is 8-chlorotheophylline compound with 2(diphenylmethoxy)-N,N-dimethylethylamine (1:1), and the structural formula is:



$C_{17}H_{21}NO \cdot C_7H_7ClN_4O_2$ **M.W. 469.96**

Dimenhydrinate Injection, USP contains a sterile solution of Dimenhydrinate 50 mg/mL; Propylene Glycol 50%; Benzyl Alcohol 5% as preservative; and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.

CLINICAL PHARMACOLOGY

While the precise mode of action of dimenhydrinate is not known, it has a depressant action on hyperstimulated labyrinthine function.

INDICATIONS AND USAGE

Dimenhydrinate Injection, USP is indicated for the prevention and treatment of nausea, vomiting, or vertigo of motion sickness.

CONTRAINDICATIONS

Neonates and patients with a history of hypersensitivity to dimenhydrinate or its components (diphenhydramine or 8-chlorotheophylline) should not be treated with dimenhydrinate.

Note: This product contains Benzyl Alcohol. Benzyl Alcohol has been associated with a fatal “Gasping Syndrome” in premature infants and infants of low birth weight.

WARNINGS

Caution should be used when dimenhydrinate is given in conjunction with certain antibiotics that may cause ototoxicity, since dimenhydrinate is capable of masking ototoxic symptoms, and an irreversible state may be reached.

This drug 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 concomitant use of alcohol or other central nervous system depressants may have an additive effect. Therefore, patients should be warned accordingly.

Dimenhydrinate should be used with caution in patients having conditions which might be aggravated by anticholinergic therapy (i.e., prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, bladder neck obstruction, narrow-angle glaucoma, bronchial asthma, or cardiac arrhythmias).

The preparation should not be injected intra-arterially.

Pediatric Patients

For infants and children especially, antihistamines in overdosage may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in pediatric patients. In the young child, particularly, they may produce excitation (see **CONTRAINDICATIONS**).

PRECAUTIONS

General

Drowsiness may be experienced by some patients, especially with high dosage. This effect frequently is not undesirable in conditions for which the drug is used.

Information for Patients

Because of the potential for drowsiness, patients taking dimenhydrinate should be cautioned against operating automobiles or dangerous machinery (see **WARNINGS**).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Mutagenicity screening tests performed with dimenhydrinate, diphenhydramine, and 8-chlorotheophylline produced positive results in the bacterial systems and negative results in the mammalian systems. There are no human data that indicate dimenhydrinate is a carcinogen or mutagen or that it impairs fertility.

Pregnancy

Pregnancy Category B.

Reproduction studies have been performed in rats at doses up to 20 times the human dose, and in rabbits at doses up to 25 times the human dose (on a mg/kg basis), and have revealed no evidence of impaired fertility or harm to the fetus due to dimenhydrinate. There are no adequate and well-controlled studies in pregnant women. However, clinical studies in pregnant women have not indicated that dimenhydrinate

increases the risk of abnormalities when administered in any trimester of pregnancy. It would appear that the possibility of fetal harm is remote when the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, dimenhydrinate should be used during pregnancy only if clearly needed.

Labor and Delivery

The safety of dimenhydrinate given during labor and delivery has not been established. Reports have indicated dimenhydrinate may have an oxytocic effect. Caution is advised when this effect is unwanted or in situations where it may prove detrimental.

Nursing Mothers

Small amounts of dimenhydrinate are excreted in breast milk. Because of the potential for adverse reactions in nursing infants from dimenhydrinate, 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.

ADVERSE REACTIONS

The most frequent adverse reaction to dimenhydrinate is drowsiness. Dizziness may also occur. Symptoms of dry mouth, nose and throat, blurred vision, difficult or painful urination, headache, anorexia, nervousness, restlessness or insomnia (especially in pediatric patients), skin rash, thickening of bronchial secretions, tachycardia, epigastric distress, lassitude, excitation, and nausea have been reported.

OVERDOSAGE

Drowsiness is the usual clinical side effect. Convulsions, coma, and respiratory depression may occur with massive overdosage. No specific antidote is known. If respiratory depression occurs, mechanically assisted respiration should be initiated and oxygen should be administered. Convulsions should be treated with appropriate doses of diazepam. Phenobarbital (5 to 6 mg/kg) may be given to control convulsions in pediatric patients.

The oral LD_{50} in mice and rats is 203 mg/kg and 1320 mg/kg, respectively. The intraperitoneal LD_{50} in mice is 149 mg/kg.

DOSAGE AND ADMINISTRATION

Dimenhydrinate in the injectable form is indicated when the oral form is impractical.

Adults

Nausea or vomiting may be expected to be controlled for approximately 4 hours with 50 mg, and prevented by a similar dose every 4 hours. Its administration may be attended by some degree of drowsiness in some patients, and 100 mg every 4 hours may be given in conditions in which drowsiness is not objectionable or is even desirable.

For intramuscular administration, each milliliter (50 mg) of solution is injected as needed, but for intravenous administration, each milliliter (50 mg) of solution must be diluted in

10 mL of 0.9% Sodium Chloride Injection, USP and injected over a period of 2 minutes.

Pediatric

For intramuscular administration, 1.25 mg/kg of body weight or 37.5 mg/m ^{2} of body surface area is administered four times daily. The maximum dose should not exceed 300 mg daily (see **CONTRAINDICATIONS**).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

DimenhyDRINATE Injection, USP, 50 mg/mL is available in multiple dose amber vials, as follows:

Product No.	**NDC No.**	**Strength**	**Vial Size**
361601	63323-366-01	50 mg/mL	1 mL in 2 mL vial, in packages of 25.
361610	63323-366-10	50 mg/mL	10 mL in a 10 mL vial, packaged individually.

Protect from light.

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

Vial stoppers do not contain natural rubber latex.

APP
APP Pharmaceuticals, LLC
Schaumburg, IL 60173

45981B

Revised: April 2008

PACKAGE LABEL - PRINCIPAL DISPLAY - Dimenhydrinate 1 mL Vial Label

NDC 63323-366-01

361601

DimenhyDRINATE *INJECTION, USP*

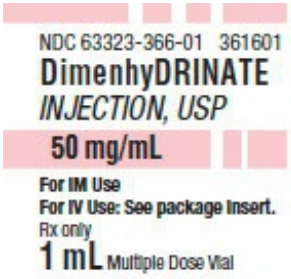
50 mg/mL

For IM Use

For IV Use: See package insert.

Rx only

1 mL Multiple Dose Vial



PACKAGE LABEL - PRINCIPAL DISPLAY - Dimenhydrinate 1 mL Vial Tray Label

NDC 63323-366-01

361601

DimenhyDRINATE *INJECTION, USP*

50 mg/mL

For IM Use

***For IV Use**

Rx only

1 mL Multiple Dose Vial

DIMENHYDRINATE
dimenhydrinate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-366
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (CHLORTHEOPHYLLINE - UNII:GE2UA340FM)	DIMENHYDRINATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.05 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 mL in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-366-01	25 in 1 TRAY	11/29/2004	
1		1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040519	11/29/2004	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	manufacture(63323-366)

Revised: 10/2024 Fresenius Kabi USA, LLC