CHLO HIST- chlophedianol hydrochloride, dexbrompheniramine maleate liquid
A-S Medication Solutions

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Chlo Hist Oral Solution

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Chlophedianol Hydrochloride 12.5 mg

Dexbrompheniramine Maleate 1 mg

Purpose

Cough Suppressant

Antihistamine

Uses A nonnaracotic cough suppressant and antihistamine for the temporary relief of:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Warnings

Do not exceed recommended dosage.

- May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when diving a motor vehicle or operating machinery.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizes may increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 6 hours, not to exceed 4 doses in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 doses in 24 hours
Children under 6 years of age:	Consult a Physician.

Other information

Store at 59°-86°F (15°-30°C)

Inactive ingredients

Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

Serious side effects associated with use of this product may be reported to this number. Call 1-423-493-9170 (8 a.m. to 5 p.m.)

Chlophedianol Hydrochloride, Dexbrompheniramine Maleate

CHLO HIST

chlophedianol hydrochloride, dexbrompheniramine maleate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3998(NDC:12830-864)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 5 mL
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3998-0	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/15/2014	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3998)

Revised: 1/2019 A-S Medication Solutions