

CHLO HIST- chlophedianol hydrochloride, dextbrompheniramine maleate liquid

R. A. McNeil Company

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

Dextbrompheniramine 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 driving 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 tranquilizers 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.)

Product Package Label for 473 mL

NDC 12830-864-16

Chlo H1st**Oral Solution**

- Cough Suppressant
- Antihistamine

Grape Flavor

EACH 5 mL (1 TEASPOONFUL)

CONTAINS:

Chophedianol

Hydrochloride.....12.5 mg

Dexbrompheniramine

Maleate.....1 mg

Alcohol Free/Gluten Free

Sugar Free/Dye Free

ONE PINT (473 mL)

Mfg. for R.A. McNeil Company

Chattanooga, TN 37406-3738

Rev. 09/17

Tamper evident by foil seal under cap. Do not
use if foil seal is broken or missing.

Dispense in a tight, light-resistant container
with a child-resistant cap.

**THIS BOTTLE IS NOT TO BE DISPENSED TO
THE CONSUMER.**

Manufactured for:

R.A. McNeil Company

1150 Latta Street

Chattanooga, TN 37406-3738

US Patent # 9,050,289

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Drug Facts (continued)

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CHLO HIST

chlorphedianol hydrochloride, dexbrompheniramine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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 (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:12830-864-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		09/15/2014	
2	NDC:12830-864-20	20 mL in 1 BOTTLE; Type 0: Not a Combination Product		09/15/2014	
3	NDC:12830-864-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		10/20/2017	
Marketing Information					
Marketing Category		Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final		part341		09/15/2014	

Labeler - R. A. McNeil Company (008305220)

Establishment			
Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(12830-864)

Revised: 1/2020

R. A. McNeil Company