

CHLOPHEDIANOL HYDROCHLORIDE, DEXCHLORPHENIRAMINE MALEATE, AND PSEUDOEPHEDRINE HYDROCHLORIDE- chlophedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride liquid Westminster Pharmaceuticals, LLC

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.

chlophedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	Purpose
Chlophedianol Hydrochloride 12.5 mg	Cough Suppressant
Dexchlorpheniramine Maleate 1 mg	Antihistamine
Pseudoephedrine Hydrochloride 30 mg	Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

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

Warnings

Do not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes

Ask a doctor 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
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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 every 6 hours, not to exceed 8 teaspoonfuls in 24 hours.
children 6 to under 12 years of age:	1 teaspoonful every 6 hours, not to exceed 4 teaspoonfuls in 24 hours.
children under 6 years of age:	consult a doctor

Other Information

- Store at room temperature 68°-86°F (20°-30°C) with excursions of 59°-86°F (15°-30°C)

Inactive ingredients

citric acid anhydrous, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose.

Questions or Comments?

Call weekdays from 9 AM to 5 PM EST at 1-844-7294. You may also report serious side effects to this phone number.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 69367-183-16

Chlophedianol HCl,
Dexchlorpheniramine
Maleate and
Pseudoephedrine HCl

Cough Suppressant
Antihistamine
Nasal Decongestant

Sugar Free, Alcohol Free,
Dye Free

Tutti Frutti Flavor

EACH 5 mL (1 TEASPOONFUL) CONTAINS:

Chlophedianol Hydrochloride 12.5 mg
Dexchlorpheniramine Maleate 1 mg
Pseudoephedrine Hydrochloride 30 mg

16 fl. oz. (473 mL)

Westminster
Pharmaceuticals

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

THIS BOTTLE IS NOT TO BE DISPENSED TO CONSUMER.

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

Manufactured for:

Westminster Pharmaceuticals LLC.

Nashville TN, 37217

Rev. 05/21

US Patent # 9,050,289

NDC 69367-183-16

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WP Westminster
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Manufactured for:
Westminster Pharmaceuticals LLC.
Nashville TN, 37217
Rev. 05/21

CHLOPHEDIANOL HYDROCHLORIDE, DEXCHLORPHENIRAMINE MALEATE, AND PSEUDOEPHEDRINE HYDROCHLORIDE

chlorphedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69367-183
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
DEXCHLORPHENIRAMINE MALEATE (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	1 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C00X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-183-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/29/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part341	07/29/2021	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2021

Westminster Pharmaceuticals, LLC