

BICLORA - chlophedianol hydrochloride, chlorcyclizine hydrochloride liquid

Physicians Total Care, Inc.

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.

biclora Liquid

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Chlophedianol Hydrochloride 12.5 mg

Chlorcyclizine Hydrochloride 12.5 mg

Purpose

Antitussive

Antihistamine

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
- calms the cough control center and relieves coughing
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Warnings

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
- difficulty in urination due to the enlargement of the 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 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

Keep out of reach of children.

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

Directions

Do not exceed recommended dosage.

Use a calibrated measuring device for administering the drug to a child.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 6 to 8 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 to 8 hours, not to exceed 3 teaspoonfuls in 24 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F).
[See USP Controlled Room Temperature].

Inactive ingredients

Cherry Flavor, Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sorbitol, Sucralsoe.

Questions? Comments?

To report a serious adverse event or obtain product information, contact 1-888-455-5253.

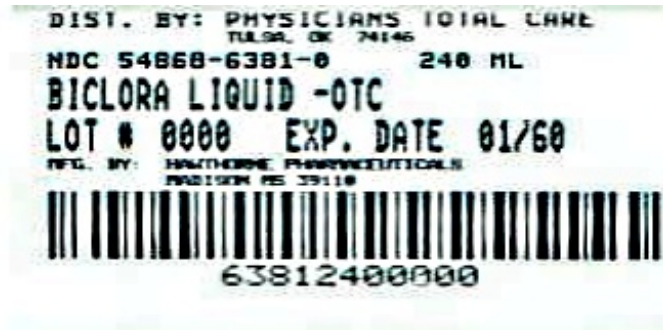
Manufactured for:
Hawthorn Pharmaceuticals,
Madison, MS 39110
HI282 Rev. 12/11

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel for 8 fl oz. label:

NDC 54868-6381-0



biclora LIQUID

Antitusive · Antihistamine

Each teaspoonful (5 mL) contains:

Chlophedianol HCl.....12.5 mg

Chlorcyclizine HCl.....12.5 mg

For professional use.

The labeling for this product includes professional labeling which is not intended for use by the general public.

Patent Pending

Alcohol Free · Dye Free

Cherry Flavor

HAWTHORN
PHARMACEUTICALS, INC.

8 fl oz (240 mL)

Distributed by:
Physicians Total Care, Inc.
Tulsa, OK 74146

BICLORA

chlophedianol hydrochloride, chlorcyclizine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-6381(NDC:63717-331)
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	
Chlorcyclizine Hydrochloride (UNII: NPB7A7874U) (Chlorcyclizine - UNII:M26C4IP44P)		Chlorcyclizine Hydrochloride	12.5 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)				
Sorbitol (UNII: 506T60A25R)				
Sucralose (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-6381-0	240 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		01/02/2013	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-6381)