DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine 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.

Active ingredient (in each 5 mL teaspoonful)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- itching of the nose or throat
- runny nose
- itchy, watery eyes
- temporarily relieves these symptoms due to the common cold:
- sneezing
- runny nose

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

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

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

- if needed, take every 4-6 hours
- do not take more than 6 doses in 24 hours

children under 4 years of age	do not use
children 4 to under 6 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	1 to 2 teaspoonfuls (12.5 mg to 25 mg)
adults and children 12 years of age and over	2 to 4 teaspoonfuls (25 mg to 50 mg)

Other information

- each teaspoonful contains: sodium 15 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

citric acid, D&C red no. 33, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol

Questions or comments?

1-800-719-9260

Principal Display Panel

Diphenhydramine Hydrochloride

12.5 mg/ 5 mL

NDC 54868-5622-0



Relieves: Sneezing Itchy, Watery Eyes Runny Nose Itchy Throat See New Warning and Dosing Directions Cherry Flavored 4 fl oz (118 mL) Alcohol Free

Additional barcode labeling by:

Physicians Total Care, Inc. Tulsa, Oklahoma 74146

DIPHENHYDRAMI		RIDE			
liphenhydramine hydrochloi	ride liquid				
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source	Item Code (Source) NDC:54868-56220		
Route of Administration	ORAL				
Active Ingredient/Activ	e Moiety				
	Ingredient Name		Basis of Stren	gth Strengt	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE DIPHENHYDRA				12.5 mg in 5 mL	
Inactive Ingredients					
	Strength				
CITRIC ACID MONOHYDRAT					
D&C RED NO.33 (UNII: 9DBA0SBB0L)					
FD&C RED NO. 40 (UNII: WZB	9127XOA)				
GLYCERIN (UNII: PDC6A3C0O					
HIGH FRUCTO SE CORN SYRI					
POLOXAMER 407 (UNII: TUF2	PIVW3M2)				
WATER (UNII: 059QF0KO0R)					
SODIUM BENZOATE (UNII: OJ					
SODIUM CHLORIDE (UNII: 451					
SODIUM CITRATE (UNII: 1Q73	- ,				
SORBITOL (UNII: 506T60A25)	R)				
Product Characteristics					
Color R	RED (Bluish-Red)	Score	2		
Shape		Size			
Flavor C	CHERRY	Impri	nt Code		

Contains					
Packaging					
# Item Code	Package Description	Marketing Start Date		Marketing End Date	
1 NDC:54868-5622-0	1 in 1 CARTON				
1	118 mL in 1 BOTTLE				
Marketing Info	rmation				
Marketing Category	Application Number or Monograph Citation		Marketing Start Da	ate Marketing End Date	
OTC monograph final	art341		06/29/2006		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment								
Name	Address	ID/FEI	Business Operations					
Physicians Total Care, Inc.		194123980	relabel					

Revised: 6/2012

Physicians Total Care, Inc.