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.

Hydramine Liquid 0182-6168-40

Drug Facts

Active ingredient (in each teaspoon (5 mL))

Diphenhydramine HCl USP 12.5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

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

Ask a doctor before use if you have

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

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

When using this product

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

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years and over	2 to 4 teaspoons (25 mg to 50 mg)	
children 6 to under 12 years	ask a doctor	
Children 4 to 5 years	do not use unless directed by a doctor	
children under 4 years	do not use	

Other information

- each teaspoon (5 mL) contains: sodium 5 mg
- store between 20°-25°C (68°-77°F). Protect from light.

Inactive ingredients

artificial cherry flavors, citric acid, D&C Red #33, FD&C Red #40, glycerin, polysorbate 20, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution

Questions?

call 1-888-838-2872, weekdays, 8 AM - 5 PM Eastern Time

PRINCIPAL DISPLAY PANEL

NDC 54868-1227-0



TAMPER-EVIDENT

Diphenhydramine HCl USP 12.5 mg per 5 mL)

ONE PINT (473 mL)

ANTIHISTAMINE

ALCOHOL-FREE SUGAR-FREE CHERRY-FLAVORED

TAMPER-EVIDENT: Do not use this product if inner foil seal over the mouth of the bottle

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-1227(NDC:0182-6168)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine	12.5 mg in 5 mL		

Inactive Ingredients				
Ingredient Name	Strength			
citric acid monohydrate (UNII: 2968PHW8QP)				
D&C Red no. 33 (UNII: 9DBA0SBB0L)				
FD&C Red no. 40 (UNII: WZB9127XOA)				
glycerin (UNII: PDC6A3C0OX)				
polysorbate 20 (UNII: 7T1F30V5YH)				
water (UNII: 059QF0KO0R)				
sodium benzoate (UNII: OJ245FE5EU)				
SACCHARIN SO DIUM DIHYDRATE (UNII: SB8 ZUX40 TY)				
sodium citrate (UNII: 1Q73Q2JULR)				
sorbitol (UNII: 506T60A25R)				

Product Characteristics			
Color	PINK	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1227-0	473 mL in 1 BOTTLE, PLASTIC		
2	NDC:54868-1227-2	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/22/2002	

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.