# ALLERGY CHILDRENS- diphenhydramine hydrochloride liquid We Care Distributors 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.

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## We Care Allergy Drug Facts

# Active ingredient (in each 5 mL)\*

Diphenhydramine HCl 12.5 mg

\*5 mL = 1 teaspoon (tsp)

# 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
- temporarily relieves these symptoms due to common cold:
- runny nose
- sneezing

#### 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

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

# 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 or tranquilizers may increase drowsiness
- be careful when operating 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 reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### **Directions**

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

Age (yr)	Dose
Adult and children 12	10-20 mL
years of age and over	(25 to 50 mg)
Children 6 to under	5-10 mL
12 years of age	(12.5 to 25 mg)
Children under 6 years of age	Ask a doctor

#### Other information

- store at room temperature 15-30°C (59-86°F)
- protect from freezing
- protect from light
- each teaspoon (5 mL) contains: sodium 16 mg

# **Inactive ingredients**

citric acid, D&C red #33, FD&C red #40, flavor, glycerin, high fructose corn syrup, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sodium sacchrin, sorbitol, sucrose

#### Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

# **Principal Display Panel**

Compare to the active ingredient in Children's Benadryl® Allergy Liquid

See New Warnings and Directions

CHILDREN'S ALLERGY

LIQUID MEDICATION

DIPHENHYDRAMINE HCl

**ORAL SOLUTION** 

**ANTIHISTAMINE** 

Relieves: Sneezing, Runny nose, Itchy, watery eyes, Itchy throat

Cherry Flavored

Alcohol Free



#### ALLERGY CHILDRENS

diphenhydramine hydrochloride liquid

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70005-036 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	RED (Bluish-Red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

II	Packaging			
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
П	1 NDC:70005-036-01	1 in 1 CARTON	06/21/2016	
	1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	ting Category Application Number or Monograph Citation		Marketing End Date
OTC monograph final	part341	06/21/2016	

# **Labeler** - We Care Distributors Inc. (079832998)

Establishment				
Name	Address	ID/FEI	Business Operations	
Purine Pharma		019950491	manufacture(70005-036)	

Revised: 8/2016 We Care Distributors Inc.