

CHILDRENS ALLERGY RELIEF- diphenhydramine hydrochloride solution CARDINAL HEALTH

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.

Children's Allergy Relief Cherry Flavor

Drug Facts

Active ingredient (in each 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 the child has

- a breathing problem such as chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Keep out of reach of children.

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

Directions

- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- ml = milliliter

Age (yr)	Dose (mL)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5mL to 10 mL

Attention: use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

Other information

- each 5 mL contains: **sodium 11 mg**
- store at room temperature
- see bottom panel for lot number and expiration date
- protect from light
- contains low sodium

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, FD&C red 40, flavors, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose.

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

LEADER™

NDC 70000-0245-1

**COMPARE TO CHILDREN'S
BENADRYL® active ingredient***

Children's Allergy Relief

Diphenhydramine HCl | Antihistamine
12.5 mg/5 mL Oral Solution

Cherry Flavor

For Relief of:

Runny Nose,
Itchy Throat or Nose,
Sneezing,
and
Itchy, Watery Eyes

4 FL OZ (118 mL)

DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING

*This product is not manufactured or distributed by Johnson and Johnson, owner of the registered trademark Children's Benadryl®.

IMPORTANT: Keep this carton for future reference on full labeling.

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CHILDRENS ALLERGY RELIEF

diphenhydramine hydrochloride solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:7000-0245

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine hydrochloride (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine hydrochloride	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
water (UNII: 059QF0KOOR)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0245-1	1 in 1 CARTON	05/02/2017	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/02/2017	

Labeler - CARDINAL HEALTH (063997360)