# SHOPRITE CHILDRENS ALLERGY- diphenhydramine hcl solution Wakefern Food Corporation

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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# **ShopRite Children's Allergy Drug Facts**

#### Active ingredient (in each 5 mL)

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

#### **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 the child has

- a breathing problem such as chronic bronchitis
- glaucoma
- a sodium-restricted diet

#### Ask a doctor or pharmacist before use if the child is

taking sedatives or tranquilizers

### When using this product

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

#### 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**

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

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	5 mL to 10 mL

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

#### Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used.
- do not use if printed neckband is broken or missing

#### **Inactive ingredients**

anhydrous 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, sorbitol solution

#### Questions or comments?

1-800-SHOPRITE

# **Principal Display Panel**

Compare to: Active Ingredient in Children's Benadryl®

Children's

AGES 6-11

**ALLERGY** 

Diphenhydramine HCl 12.5 mg/5 mL Oral Solution

Antihistamine

**MULTI-SYMPTOM** 

For Relief of:

Sneezing

Runny Nose

**Itchy Throat** 

Itchy, Watery Eyes

4-6- Hours/Dose

4 FL OZ (118 mL)



# SHOPRITE CHILDRENS ALLERGY

diphenhydramine hcl solution

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-379
Route of Administration	ORAL		

	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
	$ \begin{array}{l} \textbf{DIPHENHYDRAMINE HYDRO CHLO RIDE} \ (UNII:\ TC2D6\ JAD40\ ) \ (DIPHENHYDRAMINE - UNII:8\ GTS82S83M) \end{array} $	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)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
GLYCERIN (UNII: PDC6A3C0OX)		

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

1	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:41190-379-26	1 in 1 CARTON	0 1/11/20 16		
1		118 mL in 1 BOTTLE; 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	0 1/11/20 16	

# Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2019 Wakefern Food Corporation