

CHILDRENS ALLERGY RELIEF- diphenhydramine hydrochloride solution

CVS Pharmacy

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.

Childrens Allergy Relief

Drug Facts

Active Ingredients (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:

- 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 your 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
- 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. (1-800-222-1222)

Directions

- do not take more than 6 doses in any 24 hour period.
- give the recommended number of vials below following the instructionsunder "How to Open and Use" on the side panel.
- empty each Single-Use Vial required of all liquid when dosing.

- this product does not contain directions or complete warnings for adult use.

Dosing Chart

Age	Dose (mL)
Under 2 years	Do not use
2-6 years	Consult a doctor
6-12 years	1 - 2 Single-Use Vials (5 mL Each) Every 4 - 6 hours Do not exceed 12 Vials in 24 hours

Inactive Ingredients

Citric Acid, Glycerin, Mixed Berry Flavor, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Strawberry Flavor, Sucralose, Tri-Sodium Citrate, Xanthan Gum.

Questions or Comments?

1-800-719-9260

Other Information

- each Single-Use Vial contains 12mg of sodium.
- store at 20-25 °C (68-77 °F)
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.

Package Labeling:

Drug Facts

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Diphenhydramine HCL 12.5 mg	Antihistamine

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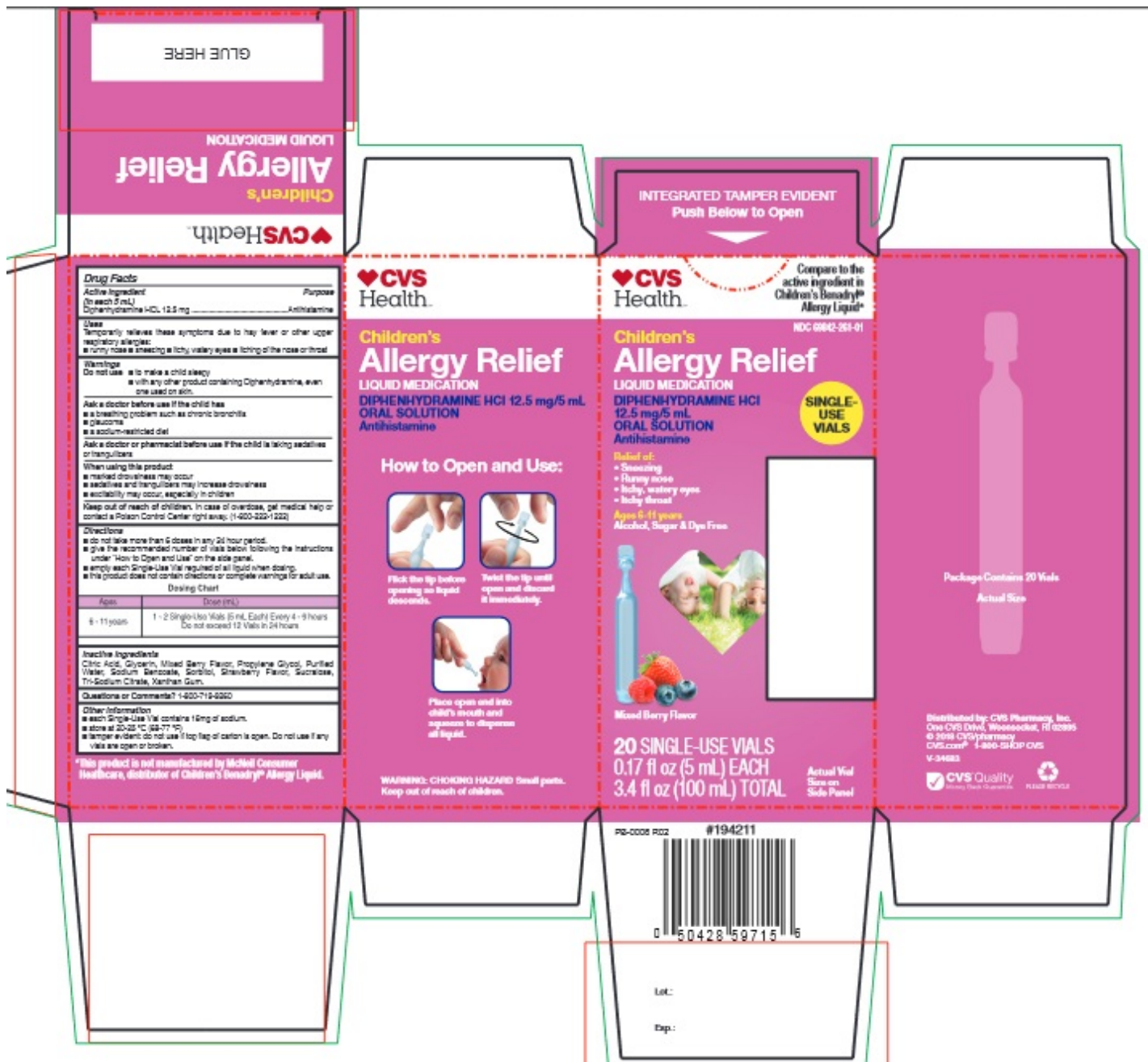
Dosing Chart

Ages	Dose (mL)
6 - 11 years	1 - 2 Single-Use Vials (5 mL Each) Every 4 - 6 hours Do not exceed 12 Vials in 24 hours

Inactive Ingredients
Citric Acid, Glycerin, Mixed Berry Flavor, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Strawberry Flavor, Sucralose, Tri-Sodium Citrate, Xanthan Gum.

Questions or Comments? 1-800-719-9260

Other Information
■ each Single-Use Vial contains 16mg of sodium.
■ store at 20-25 °C (68-77 °F)
■ tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.



CHILDRENS ALLERGY RELIEF

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-261
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-261-01	1 in 1 BOX	12/18/2018	
1		100 mL in 1 VIAL; 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	12/18/2018	

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019

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