

**CHILDRENS ALLERGY RELIEF- diphenhydramine hcl 12.5mg/5ml solution**  
**CalmCo LLC**

*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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**DrKids Childrens Allergy Relief**

**Active Ingredient (in each 5mL)**

Diphenhydramine HCL 12.5mg

**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**

**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)

**Do not use**

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

**Directions**

- this product does not contain directions or complete warnings for adult use
- give the recommended number of vials below following the instructions under Easy to Use on the side panel
- do not take more than 6 doses in any 24 hour period
- empty each Single-Use Vial of all liquid when dosing

## Dosing Chart

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Age (Years)	Dose
6-11 Years	1 - 2 Single-Use Vials (5mL each) every 4-6 hours. Do not exceed 12 vials in 24 hours

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## Inactive ingredients

citric acid, glycerin, mixed berry flavor, propylene glycol, purified water, sodium benzoate, sorbitol, strawberry flavor, sucralose, tri-sodium citrate, xanthan gum

## Other information

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

## Questions or comments?

941-202-3270 or visit [www.DrKids.com](http://www.DrKids.com)

## Package- 4ct Pouch



Vials

Ages 6-11 years

# Children's Allergy Relief

Diphenhydramine HCl 12.5 mg / 5 mL  
Antihistamine



### Relief of:

-  **Runny nose**
-  **Sneezing**
-  **Itchy eyes, nose and throat**
-  **Pre-measured dose**



**4**  **Pre-Measured Single-Use Vials**  
 0.17 fl.oz (5 mL) Each  
 0.68 fl.oz (20 mL) Total

### Free From:

- ✓ **Alcohol**
- ✓ **Dyes**
- ✓ **Sugar**



**CHOKING HAZARD**  
Small parts. Keep out of reach of children



Made in the USA: Distributed by CalmCo LLC, Sarasota FL 34240

941-202-3270 or visit www.DrKids.com

**Questions or Comments?**

### Drug Facts Continued to Side Panel

■ "Easy to Use" instructions above.  
 ■ give the recommended number of vials using the dosing chart and adult use.  
 ■ this product does not contain directions or complete warnings for

### Directions

**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)

**When using this product**

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

tranquilizers.

<b>Drug Facts</b> (continued)	
<ul style="list-style-type: none"> <li>do not take more than 6 doses in any 24 hour period.</li> <li>empty each Single-Use Vial required, of all liquid when dosing.</li> </ul>	
<b>Dosing Chart</b>	
<b>Age (Years)</b>	<b>Dose</b>
6 - 11 years	1 - 2 Single-Use Vials (5 mL Each) Every 4 - 6 hours. Do not exceed 12 Vials in 24 hours.
<b>Inactive Ingredients</b> citric acid, glycerin, mixed berry flavor, propylene glycol, purified water, sodium benzoate, sorbitol, strawberry flavor, sucralose, tri-sodium citrate, xanthan gum.	
<b>Other Information</b> <ul style="list-style-type: none"> <li>each Single-Use Vial contains 16 mg of sodium.</li> <li>store at 68-77°F (20-25°C)</li> <li>tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.</li> </ul>	

<b>Drug Facts</b>	
Keep Outer Package for Complete Product Information	
<b>Active Ingredient</b> (in each 5 mL) Diphenhydramine HCl 12.5 mg.....Antihistamine	
<b>Uses</b> 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.	
<b>Warnings</b> <b>Do not use</b> ■ to make a child sleepy. ■ with any other product containing diphenhydramine, even one used on skin. <b>Ask a doctor before use if the child has</b> <ul style="list-style-type: none"> <li>a breathing problem such as chronic bronchitis.</li> <li>glaucoma.</li> <li>a sodium-restricted diet.</li> </ul>	
<b>Ask a doctor or pharmacist before use if the child is taking sedatives or</b>	



## CHILDRENS ALLERGY RELIEF

diphenhydramine hcl 12.5mg/5ml solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73282-1254(NDC:70302-127)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL
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<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

<b>Product Characteristics</b>			
<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282-1254-1	4 in 1 POUCH	01/01/2022	
1		5 mL in 1 VIAL, SINGLE-DOSE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2022	

**Labeler** - CalmCo LLC (079308308)

**Registrant** - CalmCo LLC (079308308)