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.

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

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

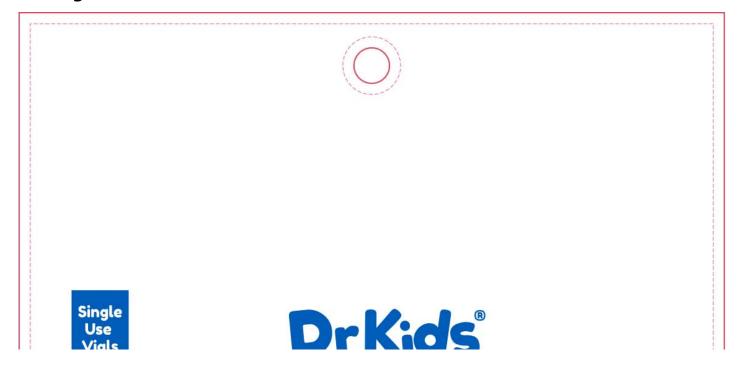
Other information

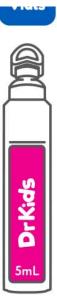
- each Single-Use vial contains 16mg of sodium
- store at 68-77°F (20-25°C)
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken

Questions or comments?

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

Package- 4ct Pocuh





Children's Allergy Relief

Ages 6-11 years

Diphenhydramine HCI 12.5 mg / 5 mL Antihistamine



Relief of:



Runny nose



Sneezing



Itchy eyes, nose and throat



Pre-measured dose



Pre-Measured Single-Use Vials 0.17 fl.oz (5 mL) Each 0.68 fl.oz (20 mL) Total Free From:

√ Alcohol

√ Dyes

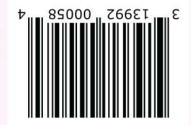
√ Sugar



DKAR-04P-001-01

CHOKING HAZARD 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?

Orug Facts Continued to Side Panel

"Easy to Use" instructions above.

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- excitability may occur, especially in children.
- sedatives and tranquilizers may increase drowsiness.
 - When using this product marked drowsiness may occur.

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Directions

Ask a doctor or pharmacist before use if the child is taking sedatives or any vials are open or broken. a sodium-restricted diet. ■ tamper evident: do not use if top flap of carton is open. Do not use if dlaucoma. ■ store at 68-77°F (20-25°C) a breathing problem such as chronic bronchitis. each Single-Use Vial contains 16 mg of sodium. Ask a doctor before use if the child has Other Information diphenhydramine, even one used on skin. xanthan gum. Do not use ■ to make a child sleepy. ■ with any other product containing sodium benzoate, sorbitol, strawberry flavor, sucralose, tri-sodium citrate, *SprimeW* citric acid, glycerin, mixed berry flavor, propylene glycol, purified water, tnactive Ingredients of the nose or throat. respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching Temporarily relieves these symptoms due to hay fever or other upper Do not exceed 12 Vials in 24 hours. 6-11 years SƏSN 1 – 2 Single-Use Vials (5 mL Each) Every 4 - 6 hours. **Antihistamine**gm &.St JOH ənimsrbydnədqiQ 9200 (Z169Y) 9gA (іп еасһ 5 ті) Dosing Char Purpose Active Ingredient ■ empty each Single-Use Vial required, of all liquid when dosing. ■ do not take more than 6 doses in any 24 hour period. Drug Facts Complete Product Information Keep Outer Package for Drug Facts (continued)

Squeeze the liquid into child's mouth



Twist to dot adt the vial off



Tap the vial to eliminate air bubbles



Easy to Use



CHILDRENS ALLERGY RELIEF

diphenhydramine hcl 12.5mg/5ml solution

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

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		
SUCRALOSE (UNII: 96K6UQ3ZD4)			
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
XANTHAN GUM (UNII: TTV12P4NEE)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

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

Marketing Information			
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)

Revised: 7/2023 CalmCo LLC