CHILDREN ALLERGY RELIEF DYE FREE CHERRY - diphenhydramine hcl solution Strategic Sourcing Services 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.

SunMark Children Allergy Relief Dye Free Cherry

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:
- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

WARNINGS

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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

- glaucoma
- a breathing problem such as chronic bronchitis

ASK A DOCTOR OR PHARMACIST BEFORE USE IF THE CHILD IS

taking sedatives or tranquilizers

WHEN USING THIS PRODUCT

- sedatives and tranquilizers may increase drowsiness
- marked drowsiness may occur
- 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

- find right dose on chart below
- mL=milliliter
- measure only with dosing cup provided
- do not use dosing cup with other products
- 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

OTHER INFORMATION

- each 5 mL contains: sodium 5 mg
- dosing cup provided
- store between 20 25°C (68°- 77°F)

INACTIVE INGREDIENTS

carboxymethylcellulose sodium, citric acid, flavors, glycerin, purified water, saccharin sodium, sodium benzoate, sorbitol.

QUESTIONS OR COMMENTS?

Call **833-358-6431** Monday to Friday 9:00 am to 7:00 pm EST

PRINCIPAL DISPLAY PANEL

SUNMARK®

COMPARE TO CHILDREN'S BENADRYL®

ORAL SOLUTION ACTIVE INGREDIENT*

NDC 70677-0144-1

children's allergy relief dye-free

Relieves: Sneezing,

Runny Nose,

Itchy, Watery Eyes

& Itching of the Nose or Throat

4-6 Hours/Dose

ANTIHISTAMINE

DIPHENHYDRAMINE HCI 12.5 MG/5 mL ORAL SOLUTION

CHERRY FLAVOR

4 FL OZ(118 mL)



CHILDREN ALLERGY RELIEF DYE FREE CHERRY

diphenhydramine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0144
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	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
glycerin (UNII: PDC6A3C0OX)		
water (UNII: 059QF0KO0R)		
sodium benzoate (UNII: OJ245FE5EU)		
sorbitol (UNII: 506T60A25R)		
SACCHARIN SODIUM ANHYDROUS (UNII: 14807BK602)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 0144-1	1 in 1 CARTON	05/16/2022	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677- 0144-2	1 in 1 CARTON	05/16/2022	
2		236 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	04/22/2022		

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 5/2022 Strategic Sourcing Services LLC