SELECT HEALTH ALLERGY RELIEF CHERRY- diphenhydramine hydrochloride liquid Axcentria Pharmaceuticals, 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.

Children's ALLERGY RELIEF

Drug Facts

Active ingredient (in each 5 mL tsp)

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 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
- 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

use only enclosed dosing cup designed for use with this product. Do not use any other dosing

device.

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours
- children under 2 years: do not use
- **children 2 to 5 years:** do not use unless directed by a doctor
- **children 6 to 12 years:** 5 to 10 mL (1 to 2 tsp)

Other Information

- each teaspoon contains: sodium 14 mg
- store between 20 to 25°C (68 to 77°F)
- protect from light
- store in outer carton until contents sused.

Inactive Ingredients

anhydrous citric acid, D&C res #33, FD&C red #40, flavors, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

Questions?

Adverse drug event call (888) 933-3222

PRINCIPAL DISPLAY PANEL - 118 ML Bottle Carton

Children's ALLERGY RELIEF

HealthSelect[®]

Diphenhydramine HCl Antihistamine

For Temporary Relief of:

- Itchy, Watery Eyes
- Itchy Throat
- Runny Nose
- Sneezing

For Ages 12 and Older Alcohol Free

NET 4 FL OZ (118 ML)

NDC 49743-3001-1



SELECT HEALTH ALLERGY RELIEF CHERRY

diphenhydramine hydrochloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49743-3003

Route	of Administration	
Route	oi Aummisu auon	

Active ingredient/Active wrotety				
Ingredient Name	Basis of Strength	Strength		
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydro chlo ride	12.5 mg in 5 mL		

Inactive Ingredients				
Ingredient Name	Strength			
Citric Acid Monohydrate (UNII: 2968 PHW8 QP)				
Sodium Benzoate (UNII: OJ245FE5EU)				
Glycerin (UNII: PDC6A3C0OX)				
polyethylene glycols (UNII: 3WJQ0SDW1A)				
sodium citrate (UNII: 1Q73Q2JULR)				
sodium chloride (UNII: 451W47IQ8X)				

Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

Packaging			
# Item C	Code Package Descripti	on Marketing Start Da	te Marketing End Date
1 NDC:49743-30	003-1 118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/01/2011	

Labeler - Axcentria Pharmaceuticals, LLC. (961871501)

Establishment			
Name	Address	ID/FEI	Business Operations
Axcentria Pharmaceuticals, LLC.		961871501	MANUFACTURE