

DYE FREE CHILDRENS DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride liquid

Precision Dose, Inc.

Reference Label Set Id: 139f7be5-c361-492c-ba3a-573ced661857

Dye Free Children's Diphenhydramine HCl Liquid

Drug Facts

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

Warnings

Do not use

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

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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in 24 hours
- take every 4 to 6 hours, or as directed by a doctor
- mL = milliliter
- find the right dose on the chart below

Age (yr)	Dose (mL)
children 6 to 11 years	5 mL to 10 mL
children 2 to 5 years	do not use unless directed by a doctor
children under 2 years	do not use

Other information

- **each 5 mL contains:** sodium 8 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- protect from light.

Inactive ingredients

carboxymethylcellulose sodium, citric acid, flavor, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol

Alcohol Free, Dye Free

How Supplied

NDC 68094-022-61
5 mL per unit dose cup
One hundred (100) cups per shipper

NDC 68094-022-62
5 mL per unit dose cup
Thirty (30) cups per shipper

NDC 68094-024-62
10 mL per unit dose cup
Thirty (30) cups per shipper

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

Manufactured by:
PL Developments
Lynwood, CA 90262

Packaged by:
Precision Dose, Inc.

South Beloit, IL 61080

LI1156 Rev. 04/22

PRINCIPAL DISPLAY PANEL - 10 mL Cup Label

NDC 68094-024-59

PrecisionDose™

Children's DYE FREE
diphenhydrAMINE HCl Liquid
25 mg/10 mL

Delivers 10 mL, each 5 mL contains: sodium 8 mg
Alcohol Free, Protect from light, Hospital Use Only

Store between 20°-25°C (68°-77°F)

Do not refrigerate

Pkg. By: Precision Dose, Inc.

South Beloit, IL 61080

1158 R0



DYE FREE CHILDRENS DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-024(NDC:49580-0293)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-024-62	3 in 1 CASE	12/27/2018	10/31/2024
1		10 in 1 TRAY		
1	NDC:68094-024-59	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M012	12/27/2018	10/31/2024

Labeler - Precision Dose, Inc. (035886746)