

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride liquid
Kesin Pharma Corporation

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.

Diphenhydramine HCl 2.5mg/mL Unit Dose Cups, 12.5mg/5 mL, 25mg/10mL

DRUG FACTS

ACTIVE INGREDIENT (in each 5 mL)

Diphenhydramine HCl 12.5mg

PURPOSE

Antihistamine

USES

For the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies or allergic rhinitis.

WARNINGS

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin
- this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland

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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfin

When using this product

- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.

Keep our of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

DIRECTIONS

Adults and children 12 years of age and over: oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor.

Children 6 to under 12 years of age: oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

OTHER INFORMATION

- each 5 mL contains: 16mg of sodium
- store at 20°-25°C (68°-77°F)
- tamper evident: DO NOT use if foil on cup is missing or torn
- Alcohol Free, Dye Free, Sugar Free
- NDC 81033-003-05 (12.5mg) unit dose cup
- NDC 81033-003-10 (25 mg) unit dose cup

INACTIVE INGREDIENTS

citric acid, glycerin, propylene glycol, water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum, mixed berry flavor, strawberry flavor

QUESTIONS or COMMENTS?

Call 1-833-537-4679

HOW SUPPLIED

- NDC 81033-003-05 (12.5mg) unit dose cup
- NDC 81033-003-10 (25 mg) unit dose cup

PRINCIPAL DISPLAY PANEL

[*Barcode*]

NDC 81033-003-05

Diphenhydramine

HCl Oral Solution

Delivers 12.5mg / 5 mL

12.5mg / 5 mL

Store at 68° - 77° F

[*Lot # Exp Date*]

PKG by Kesin Pharma

Phoenix, AZ

Sugar, Alcohol, Dye Free

For Institutional Use Only

[Barcode]

[Barcode]

NDC 81033-003-10

Diphenhydramine

HCl Oral Solution

Delivers 25mg / 10 mL

12.5mg / 5 mL

Store at 68° - 77° F

[Lot #] PKG by

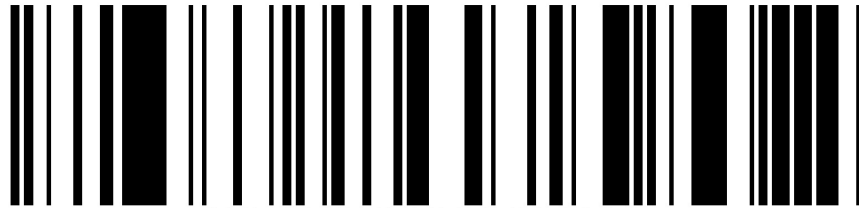
[Exp Date] Kesin Pharma

Phoenix, AZ

Sugar, Alcohol, Dye Free

For Institutional Use Only

[Barcode]



(03)8103300305(4)

NDC 81033-003-05

Diphenhydramine

HCl Oral Solution

Delivers 12.5mg | 5mL

12.5mg | 5mL

Store at 68° - 77° F

PKG By Kesin Pharma

Phoenix, AZ

Sugar, Alcohol, Dye Free

For Institutional Use





(03)8103300310(8)

NDC 81033-003-10

Diphenhydramine

HCl Oral Solution

Delivers 25mg | 10mL

12.5mg | 5mL

Store at 68° - 77° F

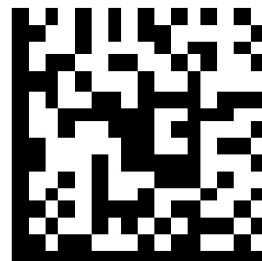
PKG By

Kesin Pharma

Phoenix, AZ

Sugar, Alcohol, Dye Free

For Institutional Use Only



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81033-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (Mixed Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-003-52	8 in 1 CASE	09/16/2021	
1	NDC:81033-003-50	50 in 1 CARTON		
1	NDC:81033-003-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-003-41	8 in 1 CASE	09/16/2021	
2	NDC:81033-003-40	40 in 1 CARTON		
2	NDC:81033-003-10	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 final	part341	09/16/2021	

Labeler - Kesin Pharma Corporation (117447816)

Revised: 1/2023

Kesin Pharma Corporation