

DIPHENHYDRAMINE ORAL SOLUTION- diphenhydramine

kci12.5mg/5ml solution

Aldama Pharmaceuticals, Inc

Diphenhydramine Oral Solution

Active ingredient (in each 5 mL-teaspoonful)

Diphenhydramine KCl 12.5mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - runny nose
 - itchy nose or throat
 - sneezing
 - itchy, watery eyes

Temporarily relieves these symptoms due to the common cold

- runny nose
- sneezing

Warnings

Do not use

with any other drug containing diphenhydramine, including one used on the skin.
to make a child sleepy

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Ask a doctor before use if you have

- a breathing problem such as chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving motor vehicle or operating machinery
- avoid alcoholic drinks

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Take every 4 hours, as needed, or as directed by a doctor
- Do not take more than 6 doses in 24 hours
- adults and children 12 years and over: 10 to 20 ml 2 to 4 teaspoonsful
- Children under 12 years: consult a doctor

Other information

- **TAMPER EVIDENT:** Do not use if foil seal over bottle opening is torn, broken or missing
- store at room temperature between 15-30°C (59-86°F)
- do not freeze
- protect from light
- Pharmacist: For dispensing, use a light-resistant container with a child-resistant cap

Inactive Ingredient

artificial and natural cherry flavor, citric acid, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Question or Comments?

305-592-9216 or info@aldamapharm.com



DIPHENHYDRAMINE ORAL SOLUTION

diphenhydramine kcl12.5mg/5ml solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73564-814
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
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

SODIUM CITRATE (UNII: 1Q73Q2JULR)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73564-814-16	1 in 1 BOX	01/01/2026	
1		473 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 Drug	M012	01/01/2026	

Labeler - Aldama Pharmaceuticals, Inc (119484030)

Establishment

Name	Address	ID/FEI	Business Operations
Aldama Pharmaceuticals, Inc		119484030	manufacture(73564-814)

Revised: 1/2026

Aldama Pharmaceuticals, Inc