

PUREGEN LABS ALLERGY RELIEF- diphenhydramine hcl liquid
Advanced Rx LLC

Puregen Allergy 201

Active ingredient (in each 5 mL teaspoonful)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

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

Warnings

Do not use

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

Ask a doctor before use if you have

- a breathing problem such as chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if the child is

taking sedatives or tranquilizers.

When using this product

- **do not exceed recommended dose**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives, and tranquilizers may increase drowsiness

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 to 6 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- use dosing cup provided.

Age Children 6 to 11 years	Dosage 5 mL to 10 mL
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Children 2 to 5 years
Children under 2 years

Do not use unless directed by a doctor
Do not use

Inactive ingredients: Artificial and natural cherry flavor, citric acid, FD&C #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose and sucrose.

Questions or comments? 1-800-630-8895

Drug Facts

Active Ingredient (in each 5 mL teaspoonful) Diphenhydramine HCl 12.5 mg	Purpose Antihistamine
USES Temporarily relieves these symptoms due to 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 product containing diphenhydramine, including ones used on the skin • to make a child sleepy 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 a motor vehicle or operating machinery • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness	
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.	

PUREGEN LABS

NDC 80513-201-16

LIQUID
ALLERGY RELIEF
DIPHENHYDRAMINE HCL 12.5 MG/5 ML

ANTIHISTAMINE

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

CHERRY FLAVOR

Compare to the active ingredient of Benadryl® Allergy Liquid*

16 FL OZ (473 ML)

Drug Facts (continued)

DIRECTIONS Do not exceed recommended dose • use dosing cup provided • take every 4 to 6 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 seal over bottle opening is torn, broken, or missing • store at room temperature 15°–30°C (59°–86°F) • do not freeze • protect from light
Inactive ingredients: Artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, and sucrose.

*This product is not manufactured or distributed by the owner of the registered trademark Benadryl®.
Questions or comments? 1-800-630-8895

Manufactured for:
ADVANCED RX LLC
1942 NE 163rd St North Miami Beach,
FL 33162 U.S.A.
L-213
Rev: 04/23

2 00055 80513 00055 3

Lot #: _____
Exp Date: _____



PUREGEN LABS ALLERGY RELIEF

diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-201
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

WATER (UNII: 059QF0KO0R)

SODIUM CITRATE (UNII: 1Q73Q2JULR)

SUCRALOSE (UNII: 96K6UQ3ZD4)

SUCROSE (UNII: C151H8M554)

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-201-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2024	

Labeler - Advanced Rx LLC (042795108)

Revised: 12/2025

Advanced Rx LLC