

CHILDRENS ALLERGY PLUS CONGESTION RELIEF- diphenhydramine hcl, phenylephrine hcl solution

Rite Aid 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.

Rite Aid Corporation Children's Allergy Plus Congestion Relief Drug Facts

Active ingredients (in each 5 mL)

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- stuffy nose
- itching of the nose or throat
- nasal congestion
- itchy, watery eyes
- temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing
- nasal congestion
- stuffy nose
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dose**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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 (1-800-222-1222).

Directions

- find right dose on chart below
- mL = milliliter
- take every 4 hours
- do not take more than 6 doses in 24 hours

Age (yr)	Dose (mL)
children under 4 years	do not use
children 4 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL contains:** sodium 10 mg
- store at 20-25°C (68-77°F). Protect from light. Store in outer carton until contents are used.
- **do not use if printed neckband is broken or missing**

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredients of Children's Benadryl® Allergy Plus Congestion

6 YEARS & OLDER

CHILDREN'S ALLERGY PLUS CONGESTION RELIEF

alcohol free - oral solution

DIPHENHYDRAMINE HCl 12.5 mg

ANTIHISTAMINE

PHENYLEPHRINE HCl 5 mg

NASAL DECONGESTANT

for relief of:

sneezing, runny, itchy or stuffy nose

itchy, watery eyes

itchy throat – sinus congestion

GRAPE FLAVOR

DOSAGE CUP INCLUDED

4 FL OZ (118 mL)



CHILDRENS ALLERGY PLUS CONGESTION RELIEF

diphenhydramine hcl, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-1119
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	PURPLE (clear)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1119-1	1 in 1 CARTON	06/21/2018	
1		118 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 final	part341	06/21/2018	

Labeler - Rite Aid Corporation (014578892)