HEALTH MART CHILDRENS ALLERGY PLUS CONGESTION- diphenhydramine hcl, phenylephrine hcl solution Strategic Sourcing Services LLC

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.

McKesson Children's Allergy Plus Congestion 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
- itchy, watery eyes
- itching of the nose or throat
- nasal congestion
- stuffy nose
- 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
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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 Children's Benadryl® Allergy Plus Congestion active ingredients

ORAL SOLUTION

Children's Allergy Plus Congestion

Antihistamine (Diphenhydramine HCl)

Nasal Decongestant (Phenylephrine HCl)

Relieves:

Runny Nose; Sneezing

Itchy, Watery Eyes; Itchy Throat or Nose

Sinus Congestion; Stuffy Nose

4 Hours/Dose • Sugar Free

Gluten Free • Alcohol Free

GRAPE FLAVOR

4 Fl oz (118 mL)



HEALTH MART CHILDRENS ALLERGY PLUS CONGESTION

diphenhydramine hcl, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0257
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SO DIUM CITRATE, UNSPECIFIED FORM (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:62011-0257-1	1 in 1 CARTON	02/12/2018	
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	0 2/12/20 18	

Labeler - Strategic Sourcing Services LLC (116956644)