

**CHILDRENS ALLERGY PLUS CONGESTION- diphenhydramine hydrochloride,
phenylephrine hydrochloride liquid
Hy-Vee**

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.

Drug Facts

Active ingredient (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, the common cold, or other upper respiratory allergies
 - runny nose
 - sneezing
 - stuffy nose
 - itchy, watery eyes
 - itching of the nose or throat
 - nasal congestion
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

- to sedate a child or 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 the child has

- 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 the child is

taking sedatives or tranquilizers.

When using this product

- do not exceed recommended dose
- marked drowsiness may occur
- avoid alcoholic beverages
- 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 get better within 7 days or are accompanied by fever

If pregnant or breast-feeding,

ask a health professional before use

Keep out of the reach of children.

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

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter
- shake well before using

Age	Dose
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 every 4 hours
adults and children 12 years and over	10 mL every 4 hours

Other information

- **each 5 mL contains:** sodium 8 mg
- store between 20-25°C (68-77°F)
- do not refrigerate. Protect from light.

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, disodium EDTA, FD&C blue #1, FD&C red #40, flavors, glycerin, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate

Questions or comments?

Call toll free **1-800-289-8343 Monday-Friday 9AM-4PM CST**

Principal Display Panel

*Compare to the Active Ingredients of Children's Benadryl® Allergy Plus Congestion
Ages 6 years and older

Children's Allergy + Congestion

Diphenhydramine HCl 12.5 mg - Antihistamine

Phenylephrine HCl 5 mg - Nasal Decongestant

SUGAR FREE • ALCOHOL FREE

Allergy & Congestion Relief

Relief of:

- Sinus Congestion
- Stuffy Nose
- Runny Nose
- Itchy, Watery Eyes
- Sneezing
- Itchy Throat or Nose

GRAPE FLAVOR

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Benadryl® Allergy Plus Congestion.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY HY-VEE, INC.

5820 WESTOWN PARKWAY

WEST DES MOINES, IA 50266

www.hy-vee.com

Product Label

Drug Facts (continued)

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PLD-A376A FC002685



Hy-Vee health

***COMPARE TO the Active Ingredients of Children's Benadryl® Allergy Plus Congestion**

NDC 42507-049-04

Ages 6 years and older

Children's Allergy + Congestion


Diphenhydramine HCl 12.5 mg - Antihistamine
Phenylephrine HCl 5 mg - Nasal Decongestant


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Allergy & Congestion Relief

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- Sneezing
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 **4 FL OZ (118 mL)**

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Hy-Vee health Children's Allergy + Congestion

CHILDRENS ALLERGY PLUS CONGESTION

diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-049
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
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ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCROSE (UNII: C151H8M554)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-049-04	1 in 1 BOX	04/30/2015	
1		118 mL in 1 BOTTLE, PLASTIC; 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	04/30/2015	

Labeler - Hy-Vee (006925671)