CHILDRENS NIGHT TIME COUGH AND COLD RELIEF- diphenhydramine hydrochloride, phenylephrine hydrochloride liquid
Chain Drug Consortium, 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.

Active ingredients

Drug Facts

Active ingredients
(in each 5 mL tsp)

Diphenhydramine HCL,USP 6.25 mg
Phenylephrine HCL, USP 2.5 mg

Purpose

Antihistamine / Cough Suppressant
Nasal Decongestant

Keep out of reach of children

Keep out of reach of children.

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

Uses

- temporarily controls cough due to minor throat and bronchial irritation and relieves nasal congestion as may occur with a cold
- temporarily relieves the following symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itchy nose or throat

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on the skin
- to make a child sleepy
- 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 two weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or a pharmacist before taking this product.

Ask a doctor before use if the child has

- heart disease

- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if the child is
- taking sedatives or tranquilizers.

When using this product
- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- nervousness, dizziness or sleeplessness occus
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of a serious condition.

Directions
- do not use more than directed
- do not take more than 6 doses in any 24-hour period
- use dosage cup or teaspoon

Age	Dose
Children 6 to under 12 years of age	2 teaspoonfuls every 4 hours
Children 4 to under 6 years of age	do not use unless directed by a doctor
Children under 4 years of age	do not use

Other information

- each teaspoonful contains: sodium 3 mg
- store between 20-25 ° C (68-77° F)
- do not refrigerate
- dosage cup provided
- **Keep carton for full directions for use**

Inactive ingredients

acesulfame potassium, citric acid anhydrous, edeate disodium, FD and C blue #1, FD and C red # 40, flavors, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST at

1-877-798-5944

Product Label

NDC 68016-143-00

***COMPARE TO THE ACTIVE INGREDIENTS IN DELSYM® CHILDREN'S NIGHT TIME COUGH and COLD**

Premier Value®
Children's Night Time

COUGH and COLD RELIEF

Diphenhydramine HCL.....Antihistamine / Cough Suppressant
Phenylephrine HCL ..... Nasal Decongestant

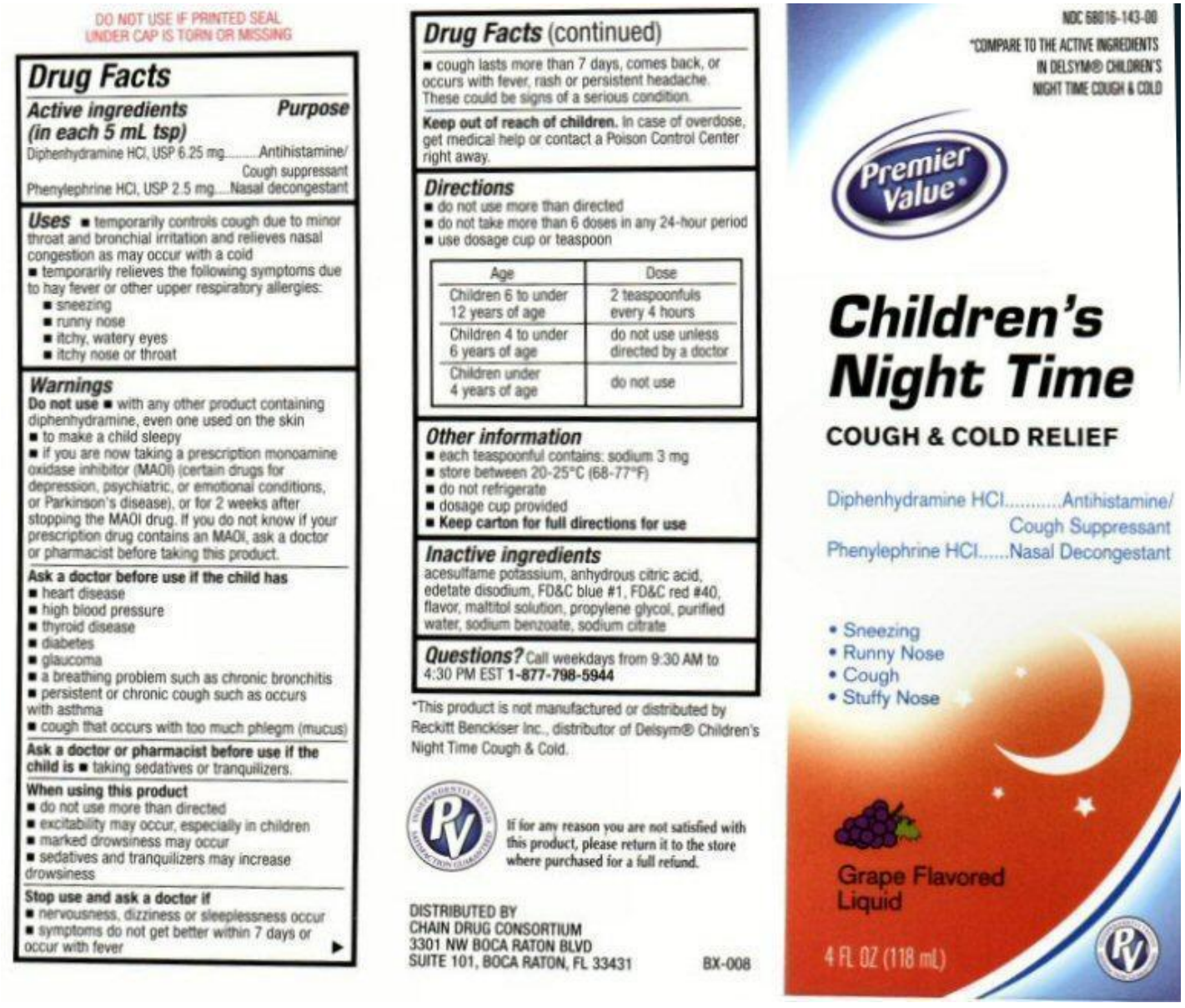
Sneezing
Runny Nose
Cough
Stuffy Nose

Grape Flavored Liquid
4 FL OZ (118mL)

INDEPENDENTLY TESTED SATISFACTION GUARANTEED PV
DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

*This product is not manufactured or distributed by Reckitt Benckiser Inc. distributor of Delsym® Children's Night Time Cough and Cold
If for Any reason you are not satisfied with this product, lease return it to the store where purchased for a full refund.

DISTRIBUTED BY
CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD
SUITE 101, BOCA RATON, FL 33431
BX-008



CHILDRENS NIGHT TIME COUGH AND COLD RELIEF

diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-143
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	6.25 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (Grape Flavored)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-143-00	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/2012	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-143)

Revised: 4/2013 Chain Drug Consortium, LLC