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 prescription drug contains an MAOI, ask a doctor or a 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 chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers.

When using this product
- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- nervousness, dizziness or sleeplessness occur
- 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.

If pregnant or breast feeding,

ask a health professional before use.

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

Age	Dose
Adults and Children 12 years of age and older	4 teaspoonfuls every 4 hours
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 tablespoonful 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, anhydrous citric acid, edetate disodium, FD and C Blue # 1, FD and C Red # 40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-5944

Product Label

NDC68016-137-00

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

Premier Value®

NIGHT TIME
COUGH and COLD RELIEF

Diphenhydramine HCL .....Antihistamine/Cough Suppressant

Phenylephrine HCL .....Nasal Decongestant
- Sneezing
- Runny Nose
- Cough
- Nasal Congestion

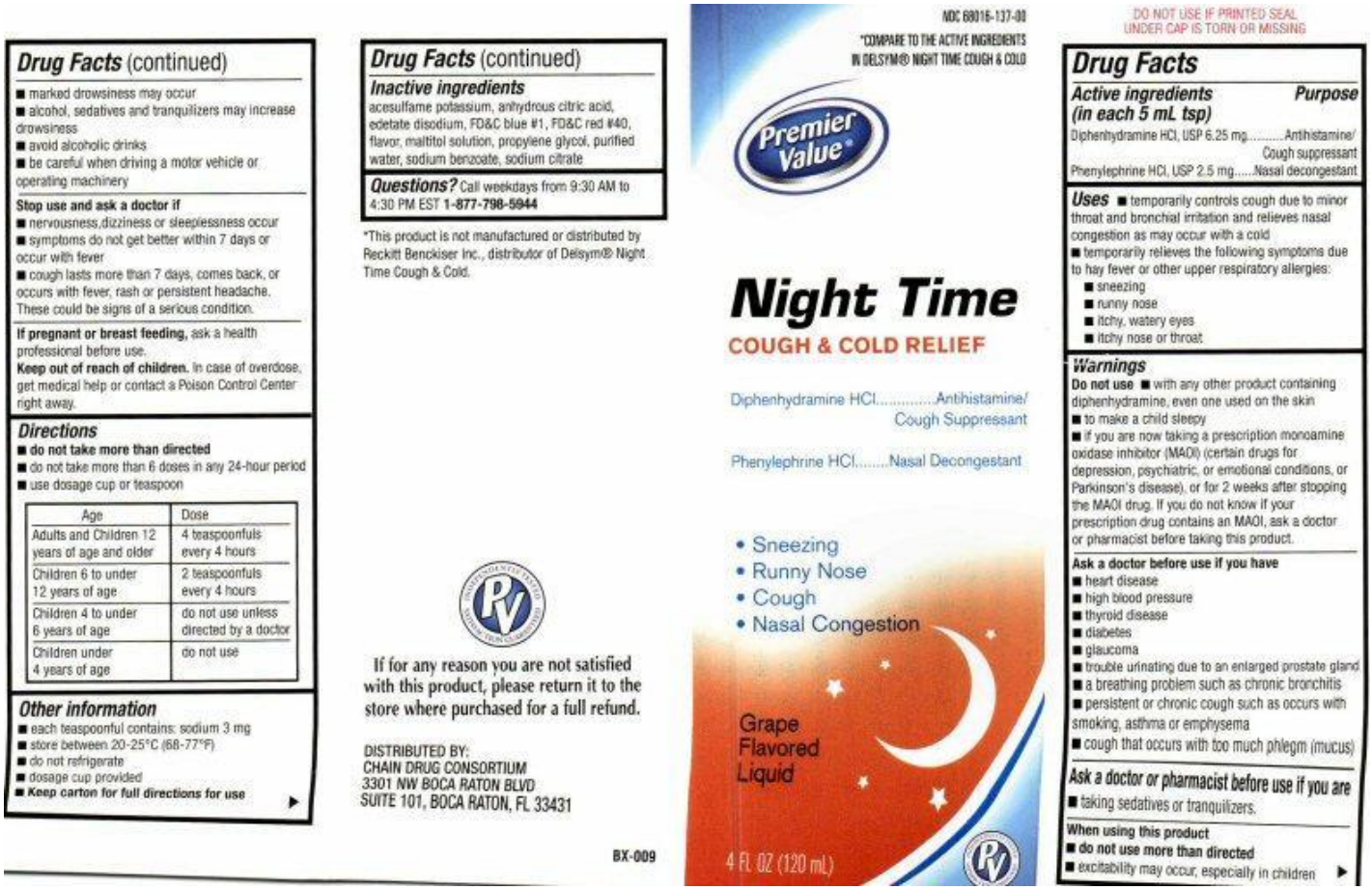
Grape Flavored Liquid
4 FL OZ (120 mL)

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 Children's Mucinex® Multisymptom Cold
If for Any reason you are not satisfied with this product, please 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-009



NIGHT TIME COUGH AND COLD RELIEF

diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-137
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 Liquid)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-137-00	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(68016-137)

Revised: 4/2013 Chain Drug Consortium, LLC