NIGHTTIME SEVERE COUGH AND COLD- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution
CARDINAL HEALTH

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.

LEADER Nighttime Severe Cough and Cold Honey Lemon 6 Packets

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine hydrochloride 25 mg

Phenylephrine hydrochloride 10 mg

Purposes

Pain reliever / fever reducer

Antihistamine / Cough Suppressant

Nasal Decongestant

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - runny nose
  - sneezing
  - itchy nose or throat
  - itchy, watery eyes due to hay fever
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

- in a child under 4 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema, asthma or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are taking

- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur
- 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 occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash or headache that lasts. There could be signs of a serious condition.

If pregnant or breast- feeding,

ask a health care professional before use.

Keep out of reach of children.

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

Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**
- take every 4 hours; not to exceed 5 packets in 24 hours or as directed by a doctor

Age	Dose
children under 4 years of age	**do not use**
children 4 to under 12 years of age	do not use unless directed by a doctor
adults and children 12 years of age and over	one packet

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10 - 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating, Do not overheat.

Other information

- **each packet contains:** potassium 6 mg
- store at controlled room temperature 20º -25ºC (68º-77ºF). Protect from excessive heat and moisture.

Inactive ingredients

citric acid, flavors, maltodextrin, potassium chloride, silica, sucralose, sucrose, yellow#6

Questions or comments?

1-866-467-2748

Additional Information Listed On Other Panels

LEADER

NDC 70000-0128-1

Nighttime **Severe Cold &Cough**

Acetaminophen

Diphenhydramine HCl

Phenylephrine HCl

Pain reliever/ Fever reducer

Antihistamine/ Cough suppressant

Nasal Decongestant

Honey Lemon

Infused with Chamomile & White Tea Flavors

Naturally and Artificially Flavored

COMPARE TO THERAFLU® NIGHTTIME SEVERE COLD & COUGH* active ingredients *

100% Money Back Guarantee

Relieves:

Nasal Congestion, Cough,
Runny Nose, Sneezing,
Body Ache, Sore Throat Pain, Headache & Fever

6 PACKETS

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE, KEEP CARTON FOR REFERENCE, DO NOT DISCARD,

NIGHTTIME **Severe Cough & Cold**

Cardinal Health™

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Essential to care™ since 1979

TAMPER EVIDENT INNER UNIT: DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.

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Principal Display

NIGHTTIME SEVERE COUGH AND COLD

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0128
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	HONEY (LEMON)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0128-1	6 in 1 CARTON; Type 0: Not a Combination Product	03/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/03/2017	

Labeler - CARDINAL HEALTH (097537435)

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