# NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine, phenylephrine powder, for solution KROGER COMPANY

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# Kroger Nighttime Severe Cold and Cough Honey Lemon 6 Packets

## Active ingredients (in each packet)

Acetaminophen, 650 mg
Diphenhydramine HCl 25 mg
Phenylephrine HCl 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

**Allergy alert:** acetaminophen may cause severe skin reactions, Symptoms may include:

- skin reddening
- blisters
- rash

**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 12 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 a 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
- 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
- taking 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 while symptoms persist, not to exceed 5 packets in 24 hours unless directed by a doctor

Age	Dose
children under 12 years of age	do not use
adults and children 12 years of age and	one packet
over	

- 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
- aspartame free, sodium free
- store at room temperature. Protect from excessive heat and moisture.

## **Inactive ingredients**

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

## Questions or comments?

1-866-467-2748

#### **Additional Information Listed On Other Panels**

## Compare to the active ingredient in Theraflu Nighttime Severe Cold & Cough\*

NDC 41226-541-06

**NIGHTTIME** 

#### **SEVERE COLD**

#### & COUGH

Acetaminophen/ Pain Reliever/ Fever Reducer

Diphenhydramine HCI /

Antihistamine/ Cough Suppressant

Phenylephrine HCI / Nasal Decongestant

#### Relieves

- Cough
- Nasal Congestion
- Sore Throat Pain
- Headache
- Body ache
- Fever
- Runny nose
- Sneezing

## **Honey Lemon**

Infused with Chamomile & White Tea Flavors

#### 6 Packets

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

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

Distributed by:

\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu Nighttime Severe Cold & Cough.

# **Principal Display**



# **NIGHTTIME SEVERE COLD AND COUGH**

acetaminophen, diphenhydramine, phenylephrine powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-541
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

## **Inactive Ingredients**

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	HONEY, LEMON	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41226-541- 06	6 in 1 CARTON; Type 0: Not a Combination Product	01/15/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	01/15/2024	

# Labeler - KROGER COMPANY (006999528)

Revised: 3/2024 KROGER COMPANY