

**SEVERE COLD AND FLU NIGHTTIME HONEY- acetaminophen,  
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid  
Kroger**

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**Kroger Nighttime Severe Cold & Flu Honey Liquid**

***Drug Facts***

***Active ingredients (in each 15 mL)***

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

***Uses*** temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

***Warnings***

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

- adult takes more than 4 doses (30 mL each) in 24 hrs, which is the maximum daily amount for this product
- child takes more than 4 doses (15 mL each) in 24 hrs, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 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

If a skin reaction occurs, stop use and seek medical help right away.

**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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- to make a child sleepy

### **Ask a doctor before use if you have**

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

### **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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days

- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over - 30 mL every 4 hrs

children 6 to under 12 yrs - 15 mL every 4 hrs

children 4 to under 6 yrs - do not use unless directed by a doctor

children under 4 yrs - do not use

**Other information**

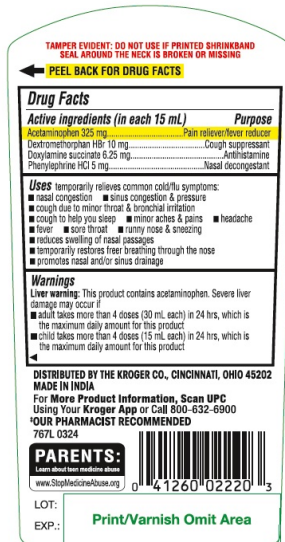
- **each 15 mL contains:** sodium 14 mg
- store at no greater than 25°C and do not refrigerate

**Inactive ingredients** citric acid monohydrate, D&C yellow no. 10, FD&C green no. 3, FD&C red no. 40, FD&C yellow no. 6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol solution, sucralose, xanthan gum

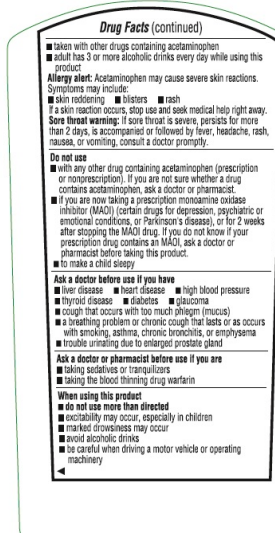
**Questions or comments? Call 1-800-632-6900**



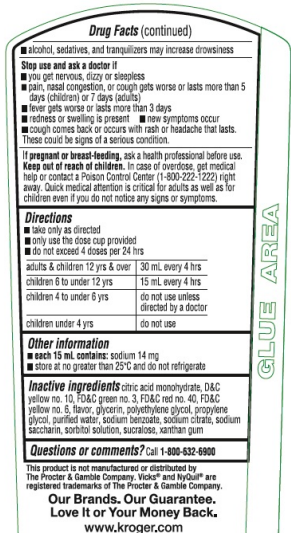
FRONT



BACK



BACK PANEL 1



BACK PANEL 2

GLUE AREA

# SEVERE COLD AND FLU NIGHTTIME HONEY

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41226-767
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	brown (clear brown color)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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<b>1</b>	NDC:41226-767-01	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2024	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012		04/30/2024	

**Labeler -** Kroger (006999528)

**Registrant -** TIME CAP LABORATORIES, INC. (037052099)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MARKSANS PHARMA LIMITED		677604129	manufacture(41226-767)

Revised: 5/2024

Kroger