

**SEVERE COLD AND FLU DAYTIME- acetaminophen, dextromethorphan hbr,  
guaifenesin, phenylephrine hcl liquid  
KROGER COMPANY**

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**Kroger Daytime Severe Cooling Liquid**

***Drug Facts***

***Active ingredients (in each 30 mL)***

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

***Uses***

- temporarily relieves common cold/flu symptoms:
  - nasal congestion
  - sinus congestion & pressure
  - cough due to minor throat & bronchial irritation
  - minor aches & pains
  - headache
  - fever
  - sore throat
  - reduces swelling of nasal passages
  - temporarily restores freer breathing through the nose
  - promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

## **Warnings**

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- taken 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

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.

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.

### **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.

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

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

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

**When using this product, do not use more than directed.**

**Stop use and ask a doctor if**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- 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 4 to under 12 yrs - ask a doctor

children under 4 yrs - do not use

**Other information**

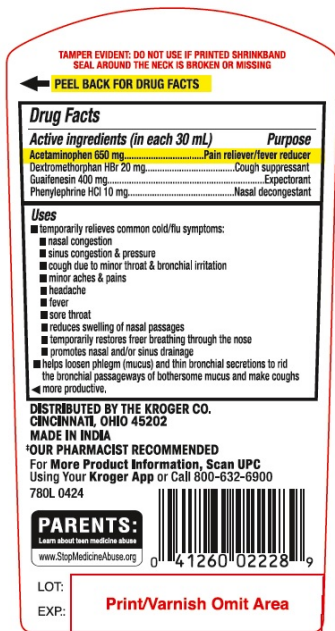
- **each 30 mL contains:** sodium 53 mg
- store at no greater than 25°C and do not refrigerate

**Inactive ingredients** citric acid monohydrate, D&C yellow no. 10, FD&C blue no. 1, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate, sodium saccharin, sorbitol solution, sucralose, xanthan gum

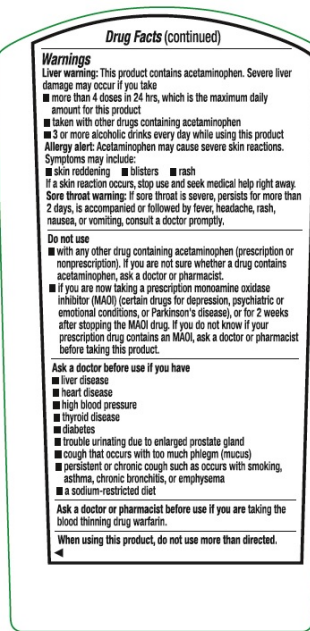
**Questions or comments? Call 1-800-632-6900**



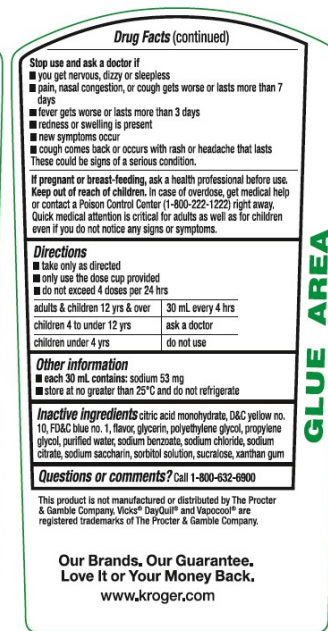
FRONT



BACK



BACK PANEL 1



BACK PANEL 2

# SEVERE COLD AND FLU DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-780
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 30 mL	
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL	
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)			
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)			
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)			
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)			
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)			
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)			
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)			

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ANISE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-780-01	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/30/2024	

**Labeler** - KROGER COMPANY (006999528)

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

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(41226-780)

Revised: 5/2024

KROGER COMPANY