

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr,
doxylamine succinate liquid
Kroger**

Kroger Nighttime Cold & Flu Cherry Liquid

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

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

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

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
-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

-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

-pain 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 6 hrs

children 4 to under 12 yrs-ask a doctor

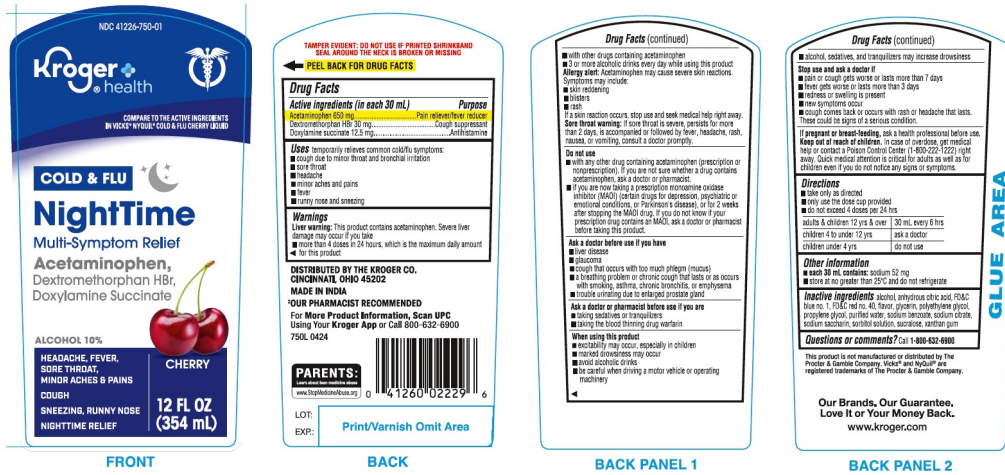
children under 4 yrs-do not use

Other information

- each 30 mL contains: sodium 52 mg
- store at no greater than 25°C and do not refrigerate

Inactive ingredients alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, 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



NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red (clear red color)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-750-01	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 (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(41226-750)

Revised: 5/2024

Kroger