NIGHTTIME COLD AND FLU- dextromethorphan hydrobromide, acetaminophen, doxylamine succinate capsule, liquid filled Kroger Company

694T KROGER 41226 694 Acetaminophen Dextromethorphan Hydrobromide Doxylamine Succinate CT 24

DRUG FACTS

Acetaminophen 325 mg Dextromethorphan Hydrobromide 15 mg Doxylamine succinate 6.25 mg

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

- temporarily relieves common cold/flu symptoms:
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

Warnings

Liver warning:

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

- more than 8 softgels in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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
- 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, & 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 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 right away (1-800-222-1222). 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
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over: 2 softgels with water every 6 hrs children 4 to under 12 yrs: ask a doctor

children under 4 yrs: do not use

OTHER INFORMATION

Other information

• store at room temperature

Inactive ingredients FD&C Blue #1, D&C yellow #10,gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water,shellac, sorbitol sorbitan solution,titanium dioxide.

Questions ? 1-800-632-6900

1720 01741

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100% SIZE 12-digit UPC-A (non-suppressed) For Position Only

BECACLE PLEASE

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CINCINNATI, OHIO 45202
FOR MORE PRODUCT INFORMATION, SCAN UPC USING YOUR
KROGER APP OR CALL BOD-632-6900 Questions? 1-800-632-6900

PARENTS:

www.StopMedicineAbuse.org

Our Brands. Our Guarantee. Love It or Your Money Back. www.kroger.com

Drug Facts

Dextromethorphan HBr 15 mg Doxylamine succinate 6.25 mg Active ingredients (in each softgel)

USPS ■temporarily relieves common cold/flu symptoms:
■ cough due to minor throat & bronchial irritation
■ sore throat ■ headache ■ minor aches & pains ■ fever

■ runny nose & sneezin

. Cough suppressant Antihistamine Purpose

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Drug Facts (continued)

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> Doxylamine Succinate Dextromethorphan HBr

Multi-Symptom Relief

Acetaminophen

Drug Facts (continued)

Cold

& Flu

Other information store at room temperature

Inactive ingredients FD&C blue #1, D&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide.







COMPARE TO the active ingredients of VICKS" NYQUIL" COLD & FLU RELIEF LIQUICAPS"

**See side panel

NDC 41226-694-24

POWERFUL NIGHTTIME RELIEF

actual size

Cough Suppressant

Antihistamine

Fever Reducer

Pain Reliever

24 SOFTGELS

Lot #:

694T 0321

SAFETY SEALED: DO NOT USE IF THE INDI

UNIT IS OPEN OR TORN

NIGHTTIME COLD AND FLU

dextromethorphan hydrobromide, acetaminophen, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-694
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SHELLAC (UNII: 46N107B710)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
GLYCERIN (UNII: PDC6A3C0OX)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
GELATIN (UNII: 2G86QN327L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SORBITAN (UNII: 6092ICV9RU)				

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL (Oblong shaped)	Size	21mm	
Flavor		Imprint Code	71	
Contains				

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41226- 694-24	2 in 1 CARTON	05/11/2021	
	1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	05/11/2021		

Labeler - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-694)	

Revised: 2/2025 Kroger Company