DAYTIME COLD AND FLU- dextromethorphan hydrobromide, acetaminophen, phenylephrine hydrochloride capsule, liquid filled Kroger Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

693T KROGER 41226 693 Acetaminophen Dextromethorphan Hydrobromide Phenylephrine Hydrochloride CT 24

Acetaminophen 325 mg Dextromethorphan Hydrobromide 10 mg Phenylephrine Hydrochloride 5 mg

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

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

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
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

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 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 hr

adults & children 12 years & over: 2 softgels with water every 4 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 red #40,FD&C yellow #6,gelatin,glycerin, polyethylene glycol, povidone,propylene glycol,purified water,shellac,sorbitol sorbitan solution,titanium dioxide.

| t1500 | 015t0

(non-süppressed) For Position Only 100% SIZE A-Dalgit UPC-A

Stop use and ask a doctor if

FOR **more product information, scan upc** using your K**roger app** or call 800-632-6900 CINCINNATI, OHIO 45202

Questions? 1-800-632-6900

Active ingredients (in each softgel) Acetaminophen 325 mg Drug Facts

www.StopMedicineAbuse.org

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

Learn about teen medicine abuse PARENTS:

Acetaminophen 325 mg..... Dextromethorphan HBr 10 mg. Phenylephrine HCl 5 mg.....

 Cough suppressant
 Nasal decongestant Purpose

**See side panel

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

temporarily relieves common cold/flu symptoms:

nasal congestion

cough due to minor throat & bronchial irritation

sore throat

headache

minor aches & pains

fever

sore throat

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■ you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough get worse or last more than 7 days ■ fever gets worse or lasts more than 3 days

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Drug Facts (continued)

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adults & children 12 yrs & over 2 softgels with water every 4 hrs children 4 to under 12 yrs ask a doctor children under 4 yrs do not use

Drug Facts (continued)

Other information store at room temperature

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide.

Cold & Flu



NON-DROWS POWERFUL

NDC 41226-693-24

RELIEF

Phenylephrine HC Dextromethorphan Acetaminophen

Multi-Symptom Relief

24 SOFTGELS

SAFETY SEALED: DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

693T 0321

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

DAYTIME COLD AND FLU

dextromethorphan hydrobromide, acetaminophen, phenylephrine hydrochloride capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-693	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SORBITOL (UNII: 506T60A25R)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
WATER (UNII: 059QF0KO0R)			
SHELLAC (UNII: 46N107B710)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERIN (UNII: PDC6A3C0OX)			
POVIDONE (UNII: FZ 989GH94E)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL (Oblong shaped)	Size	21mm
Flavor		Imprint Code	70
Contains			

_			Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	DC:41226- 93-24	2 in 1 CARTON	05/11/2021			
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	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(41226-693)	

Revised: 11/2022 Kroger Company