DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
KROGER COMPANY

Kroger Acetaminophen 325 mg, Dextromethorphan HBr 10 mg, Guaifenesin 200 mg, Phenylehrine HCl 5 mg Tablets

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:

- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

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

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

When using this product do not exceed recommended dose

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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.

Overdose warning: 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

- **do not take more than directed. (see overdose warning)**

adults and children 12 years and over	• take 2 caplets every 4 hours • swallow whole; do not crush, chew or dissolve • do not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

Other information

- each caplet contains: **sodium 3 mg**
- store at room temperature, between 20º - 25ºC (68º - 77ºF), and avoid excessive heat and humidity

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, crospovidone, D&C yellow no. 10 al. lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, talc, titanium dioxide, triacetin

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

DAYTIME COLD AND FLU

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41226-675
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow (Light yellow to yellow)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	D1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-675-24	2 in 1 CARTON	05/26/2025	
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 Drug	M012	05/26/2025	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-675)

Revised: 5/2025 KROGER COMPANY