DAYTIME NIGHTTIME ULTRA CONCENTRATED- daytime - acetaminophen, dextromethorphan hbr, phenylephrine hcl and nighttime - acetaminophen, dextromethorphan hbr, doxylamine succinate KROGER COMPANY

Kroger Daytime Nighttime Ultra Concentrated Cold and Flu Liquid filled capsules

Drug Facts

Daytime Ultra Concentrated Cold & Flu

Active ingredient (in each softgel)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Purpose

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 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
- 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, 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 8 softgels per 24 hrs

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

Other information

store at no greater than 25°C

Inactive ingredients

FD&C yellow no. 6 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call **1-800-632-6900**

Drug Facts

Nighttime Ultra Concentrated Cold & Flu

Active ingredient (in each softgel)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg

Purpose

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 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

- 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, 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 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 8 softgels per 24 hrs

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

Other information

store at no greater than 25°C

Inactive ingredients

D&C yellow no. 10 Al. lake, FD&C blue no. 1 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call **1-800-632-6900**

COLD & FLU DayTime	BETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION DURY FRAMEWORK INFORMATION USE INFORMATION INFORMATION INFORMATION USE INFORMATION INFORMATION INFORMATION DURY FRAMEWORK INFORMATION DURY FRAMEWORK INFORMATION INFORMAT	Contract and the second s
Dextromethorphan HBr-Cough Suppressant	EXP.: Print/Varnish	childrm under 4 yrs do not use
Phenylephrine HCI-Nasal Decongestant	Omit Area	Other information ■ store at no greater than 25°C
48 SOFTGELS	Omit Area	Questions or comments? Cail 1-800-832-8800



DAYTIME NIGHTTIME ULTRA CONCENTRATED

daytime - acetaminophen, dextromethorphan hbr, phenylephrine hcl and nighttime - acetaminophen, dextromethorphan hbr, doxylamine succinate kit

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-778			
Packaging						
# Item Cod	e Package Descri	ption Marketing Start Da	ate Marketing End Date			
1 NDC:41226-778-	83 1 in 1 CARTON	04/30/2025				
Quantity of Parts						
Part # Package Quantity Total Product Quantity						

Part 1 1 E	BOTTLE	48
Part 2 1 E	BOTTLE	48

Part 1 of 2

DAYTIME ULTRA CONCENTRATED COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product	Information

Item Code (Source)	NDC:41226-777
Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
SORBITAN (UNII: 6092ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
MICA (UNII: V8A1AW0880)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics					
Color	orange	Score	no score		
Shape	OVAL	Size	15mm		
Flavor		Imprint Code	151		
Contains					

Packaging

#	ltem Code	Packa	age Description		ting Start Pate	Market Da	ate
		48 in 1 BOTTLE; T Product	ype 0: Not a Combination				
		FIGUEL					
M a	arketin	g Informat	ion				
	Marketin Category		tion Number or Monograp Citation	h Ma	rketing Start Date		eting End Date
тс	Categor: Monograph	-	Citation	04/30		-	Jace
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P a	rt 2 of	2					
JI	GHTTI		CONCENTRATED CO				
	-	-	orphan hbr, doxylamine su	-	-	filled	
		formation					
			NDC:41226-756				
	m Code (S						
Route of Administration ORAL							
		linistration	ORAL				
			ORAL				
\C †	tive Ingr	edient/Active	Moiety				
		edient/Active Ingre	Moiety dient Name		Basis of S	trength	Streng
002		edient/Active Ingre	Moiety		Basis of S DOXYLAMINE SU	-	Streng 6.25 mg
DOX INII DEX	KYLAMINE S :95QB77JKP KTROMETHO	edient/Active Ingre SUCCINATE (UNII: L)	Moiety dient Name V9BI9B5YI2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH)			JCCINATE RPHAN	
DOX JNII DEX	XYLAMINE S :95QB77JKP XTROMETHO	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355>	Moiety dient Name V9BI9B5YI2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH)	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN	6.25 mg
DE)	XYLAMINE S :95QB77JKP XTROMETHO	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355>	Moiety dient Name v9Bi9B5Yi2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH) (3ROTS)	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN	6.25 mg 10 mg
DOX JNII DEX ACE	XYLAMINE S :95QB77JKP XTROMETHO XTROMETHO ETAMINOPH	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355 IEN (UNII: 36209ITI	Moiety dient Name v9Bi9B5Yi2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH) (3ROTS)	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN	6.25 mg 10 mg
DE) DE)	XYLAMINE S :95QB77JKP XTROMETHO XTROMETHO ETAMINOPH	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355>	Moiety dient Name v9Bi9B5Yi2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH) (3ROTS)	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN E	6.25 mg 10 mg
DE) DE) ACE	EXPLAMINE S :95QB77JKP CTROMETHO ETAMINOPH ETAMINOPH	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355 IEN (UNII: 36209ITI	Moiety dient Name V9BI9B5YI2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH) (3ROTS) L9D) (ACETAMINOPHEN - UNII:362	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN E	6.25 mg 10 mg 325 mg
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	XYLAMINE S :95QB77JKP CTROMETHO TROMETHO TAMINOPH ACTIVE IN ACTIVE IN RBITAN (UN YETHYLEN VIDONE (UN C YELLOW RBITOL (UN :A (UNII: V8A	edient/Active Ingre SUCCINATE (UNII: L) ORPHAN HYDROB RPHAN - UNII:7355> IEN (UNII: 36209ITI Gredients II: 6092ICV9RU) E GLYCOL, UNSPI II: FZ989GH94E) NO. 10 ALUMINUI II: 506T60A25R) (1AW0880)	Moiety dient Name V9BI9B5YI2) (DOXYLAMINE - ROMIDE (UNII: 9D2RTI9KYH) (3ROTS) L9D) (ACETAMINOPHEN - UNII: 362 Ingredient Name ECIFIED (UNII: 3WJQ0SDWLA)	O9ITL9D)	DOXYLAMINE SU DEXTROMETHOF HYDROBROMIDE	JCCINATE RPHAN E	6.25 mg 10 mg 325 mg
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Product Cha	aracteristi	cs					
Color		green	Score		no score		
Shape		OVAL	Size			15mm	
Flavor			Imprint Code			152	
Contains							
Packaging							
# Item Code	Pa	ickage Descrip	otion	Μ	arketing Start Date	Marketing End Date	
1	48 in 1 BOTTL Product	E; Type 0: Not a C.	ombination				
Markatin	a Inform	ation					
Marketin	-						
Marketing Category		lication Numbe Citati		h	Marketing Start Date	Marketing End Date	
OTC Monograph	Drug M012				04/30/2025		
Marketing Information							
Marketing Category		lication Numbe Citati		h	Marketing Start Date	Marketing End Date	
OTC Monograph	Drug M012				04/30/2025		

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-777, 41226-756, 41226-778)

Revised: 4/2025

KROGER COMPANY