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

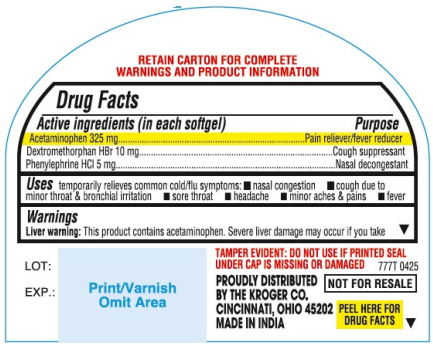
store at no greater than 25°C

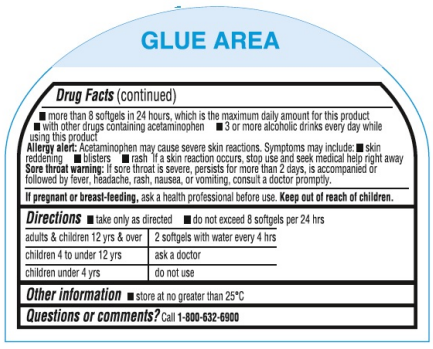
Inactive ingredients

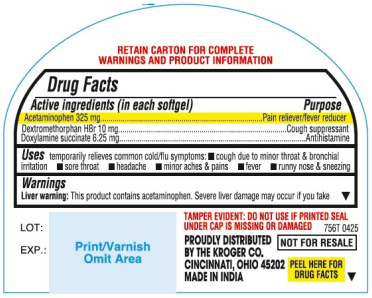
D&C yellow no. 10 Al. lake, FD&C blue no. 1 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol,
purified water, shellac, sorbitol sorbitan solution, titanium dioxide

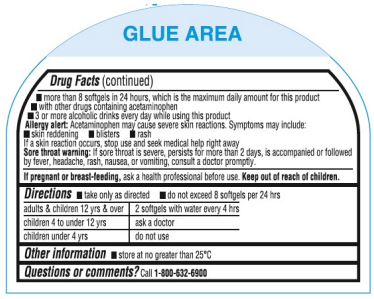
Questions or comments?

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









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 Code	Package Description	Marketing Start Date	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 BOTTLE	48
Part 2	1 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: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITAN (UNII: 6O92ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
MICA (UNII: V8A1AW0880)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 in 1 BOTTLE; 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	04/30/2025	

Part 2 of 2

NIGHTTIME ULTRA CONCENTRATED COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:41226-756
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITAN (UNII: 6O92ICV9RU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
SORBITOL (UNII: 506T60A25R)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 in 1 BOTTLE; 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	04/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	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