

**KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate**

**The Kroger Company**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Kroger Daytime and Nighttime Cold and Flu Softgel**

**DayTime Cold & Flu**

**Drug Facts**

**Active ingredients (in each Softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purposes**

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 4 doses 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, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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 get worse or last 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:** Taking more than directed can cause serious health problems. 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 & for children even if you do not notice any signs or symptoms.

**Directions:**

- take only as directed - see Overdose warning
- do not exceed 4 doses 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 room temperature between 20-25 °C (68-77 °F)

**Inactive ingredients:**

Edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments:**

**1-800-632-6900**

**NightTime Cold & Flu**

**Drug Facts**

**Active ingredients (in each Softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purposes**

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:**

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your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. • to make a child sleep

**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, & 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.

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***Other information:***

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***Inactive ingredients:***

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

***Questions or comments:***

1-800-632-6900

**COMPARE TO the active ingredients of VICKS® DAYQUIL®/NYQUIL® COLD & FLU RELIEF LIQUICAPS® \*See side panel**

**POWERFUL RELIEF**

**DAYTIME OR NIGHT TIME**

**OUR PHARMACIST RECOMMENDED**

**Multi-Symptom Relief**

**READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**DO NOT USE IF THE BLISTER IS TORN OR BROKEN OR SHOW ANY SIGNS OF TAMPERING**

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

MADE IN UAE

For **More Product Information, Scan UPC**

Using Your **Kroger App** or Call 800-632-6900

**Our Brands, Our Gurantee.**

**Love It or Your Money Back.**

[www.kroger.com](http://www.kroger.com)

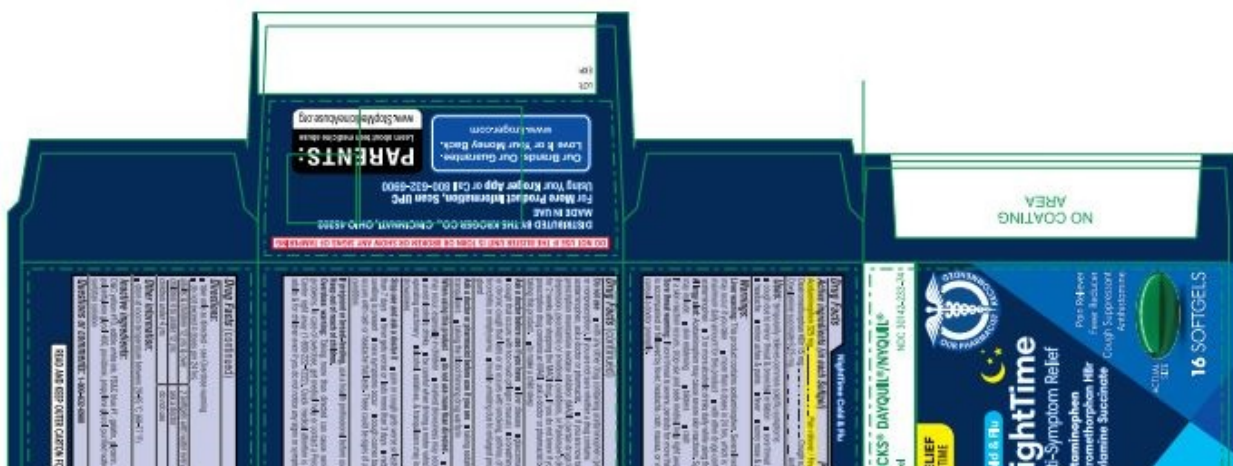
**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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## Packaging





**FRONT PANEL**



**DRUG FACTS PANEL**

<b>Drug Facts</b>	<b>NightTime Cold &amp; Flu</b>	<b>Drug Facts</b>	<b>DayTime Cold &amp; Flu</b>
<b>Active ingredients (in each Softgel)</b>	<b>Purposes</b>	<b>Active ingredients (in each Softgel)</b>	<b>Purposes</b>
Acetaminophen 325 mg.....	Pain reliever / Fever reducer	Acetaminophen 325 mg.....	Pain reliever / Fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant	Dextromethorphan HBr 10 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine	Phenylephrine HCl 5 mg.....	Nasal decongestant
<b>Uses:</b> temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> <li>■ cough due to minor throat &amp; bronchial irritation</li> <li>■ sore throat</li> <li>■ headache</li> <li>■ minor aches &amp; pains</li> <li>■ fever</li> <li>■ runny nose &amp; sneezing</li> </ul>		<b>Uses:</b> temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> <li>■ nasal congestion</li> <li>■ cough due to minor throat &amp; bronchial irritation</li> <li>■ sore throat</li> <li>■ headache</li> <li>■ minor aches &amp; pains</li> <li>■ fever</li> </ul>	
<b>Warnings:</b> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses 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 <b>Allergy alert:</b> 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. <b>Sore throat warning:</b> 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.		<b>Warnings:</b> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses 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 <b>Allergy alert:</b> 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.	
<b>Drug Facts (continued)</b>		<b>Drug Facts (continued)</b>	

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**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

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**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

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**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

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### Drug Facts (continued)

#### Directions:

- take only as directed - see Overdose warning
- 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:

- store at room temperature between 20-25 °C (68-77 °F)

#### Inactive ingredients:

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments:** 1-800-632-6900

### Drug Facts (continued)

#### Directions:

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 Softgels with water every 4 hrs
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#### Inactive ingredients:

Edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments:** 1-800-632-6900

## KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-233
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-233-74	1 in 1 KIT; Type 0: Not a Combination Product	08/31/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	4 BLISTER PACK	16

### Part 1 of 2

## KROGER DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:30142-087
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	



SORBITAN (UNII: 6O92ICV9RU)

### Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	807
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	08/31/2022	

## Part 2 of 2

### KROGER NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

### Product Information

Item Code (Source)	NDC:30142-086
Route of Administration	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	808
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	08/31/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/31/2022	

**Labeler** - The Kroger Company (006999528)