# KROGER NIGHTTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled The Kroger Company

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## **Kroger NightTime Cold and Flu Softgel**

# **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:**

# 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, is accompanied or 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. • 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.

## 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	2 Softgels with water
yrs & over	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

#### Questions or comments:

1-800-632-6900

COMPARE TO the active ingredients of VICKS® NYQUIL®

COLD & FLU NIGHTTIME RELIEF LIQUICAPS® \*See bottom panel

**POWERFUL NIGHTTIME RELIEF** 

**OUR PHARMACIST RECOMMENDED** 

**Multi-Symptom Relief** 

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN OR SHOWS ANY SIGN OF TAMPERING

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

\*This product is not manufactured or distributed by The Proctor & Gamble Company. Vicks  $^{\$}$ , NyQuil $^{\$}$ , and LiquiCaps  $^{\$}$  are registered trademarks of The Proctor & Gamble Company.

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Our Brands, Our Guarantee.

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www.kroger.com

# **Packaging**





#### DRUG FACTS TABLE

Drug Facts		
Active ingredients (in each Softgel)		Purposes
Acetaminophen 325 mg		Pain reliever / Fever reducerCough suppressantAntihistamine
Uses: temporarily relieves common cold/flu symptoms: cough due to minor throat & bronchial irritation minor aches & pains	sore throat	■ headache ■ runny nose & sneezing

#### 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
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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. . 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

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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.

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.

# 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

# **KROGER NIGHTTIME COLD AND FLU SOFTGEL**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-086

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	808
Contains			

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:30142- 086-48	4 in 1 CARTON	08/31/2022		
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	08/31/2022	

# Labeler - The Kroger Company (006999528)

Revised: 12/2024 The Kroger Company