# KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate The Kroger Co.

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 & Flu SOFTGELS

DayTime Cold & Flu

Drug Facts

#### Active ingredients (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, lasts 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, chronic bronchitis, 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.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. 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 room temperature between 20°-25°C (68°-77°F)
- protect from light, heat, and moisture

#### Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, sorbitol sorbitan anhydrous, titanium dioxide

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

#### **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 hrs, 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
   thyroid disease
   diabetes
- 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.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. 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 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)
- protect from light, heat, and moisture

## Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, polyvinyl

pyrrolidone, propylene glycol, sorbitol sorbitan anhydrous, titanium dioxide

#### **Questions or comments?**

1-800-632-6900

COMPARE TO active ingredients of VICKS<sup>®</sup> DAYQUIL<sup>®</sup>/DAYQUIL<sup>®</sup> COLD & FLU RELIEF LIQUICAPS™\*

#### **POWERFUL RELIEF**

DAYTIME OR NIGHTTIME

Multi-Symptom Relief

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND INFORMATION

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO QUALITY GUARANTEE www.kroger.com

#### PRODUCT OF INDIA

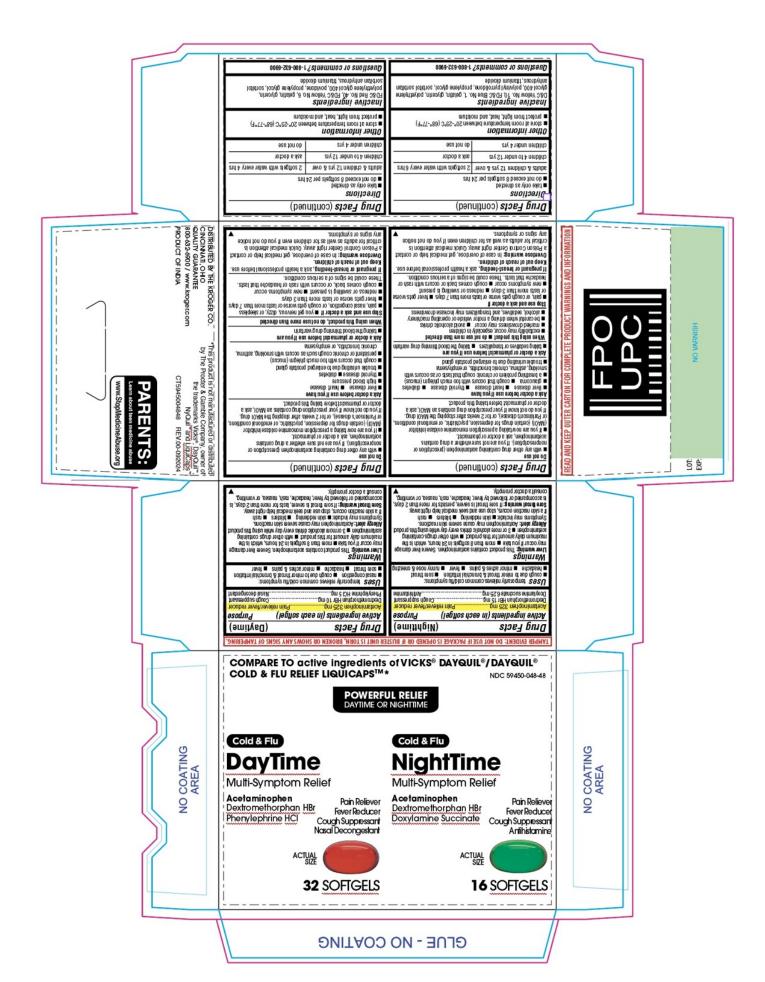
\*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the trademarks Vicks®, DayQuil™, NyQuil™ and LiquiCaps™

REV.00-092024

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org

#### **Packaging**



#### Drug Facts (Nighttime)

### Active ingredients (in each softgel)

Purpose

Acetaminophen 325 mg......Pain reliever/fever reducer Dextromethorphan HBr 15 mg......Cough suppressant Doxylamine succinate 6.25 mg......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 warming: 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 acetamin ophen 🔳 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.

## Drug Facts

(Daytime

#### Active ingredients (in each softgel)

Purpose

Acetaminophen 325 mg......Pain reliever/fever reducer Dextromethorphan HBr 10 mg......Cough suppressant Phenylephrine HCl 5 mg.......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: Acetamin ophen 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, consult a doctor promptly.

## **Drug Facts** (continued)

- 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 nowtaking 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 thyroid disease diabetes
- 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 m 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Drug Facts (continued)

- with any other drug containing acetamin ophen (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. chronic bronchitis, 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## *Drug Facts* (continued)

#### Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over | 2 soft gels with water every 6 hrs

## *Drug Facts* (continued)

#### 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

Questions or comment	s? 1-800-632-6900	Questions or comment	\$?1-800-632-6900
Inactive ingredients  D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, polyvinyl pyrrolidone, propylene glycol, sorbitol sorbitan anhydrous, titanium dioxide		Inactive ingredients FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, sorbitol sorbitan anhydrous, titanium dioxide	
Other information ■ store at room temperature between 20°-25°C (68°-77°F) ■ protect from light, heat, and moisture		Other information ■ store at room temperature between 20°-25°C (68°-77°F) ■ protect from light, heat, and moisture	
children under 4 yrs	do not use	children under 4 yrs	do not use
children 4 to under 12 yrs	ask a doctor	children 4 to under 12 yrs	ask a doctor

#### KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59450-048

# Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:59450-048- 1 in 1 CARTON; Type 0: Not a Combination Product 01/08/2025

Quant	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

<b>Product Information</b>	
Item Code (Source)	NDC:59450-046
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6092ICV9RU)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	A09
Contains			

Pa	Packaging			
#	ltem 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	01/08/2025	

## Part 2 of 2

## **KROGER NIGHTTIME COLD AND FLU SOFTGEL**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

## **Product Information**

Item Code (Source)	NDC:59450-047
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	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)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6092ICV9RU)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	902
Contains			

l	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	01/08/2025	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/08/2025	

## **Labeler -** The Kroger Co. (006999528)

Revised: 1/2025 The Kroger Co.