# KROGER DAYTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

## The Kroger Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

## Kroger DayTime Cold and Flu Softgel

## **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, 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 • high blood pressure • 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

	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

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

**POWERFUL NON-DROWSY RELIEF** 

**OUR PHARMACIST RECOMMENDED** 

**Multi-Symptom Relief** 

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
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  $^{\mathbb{B}}$ , DayQuil $^{\mathbb{B}}$ , and LiquiCaps  $^{\mathbb{B}}$  are registered trademarks of The Proctor & Gamble Company.

#### **PARENTS:**

Learn about teen medicine abuse

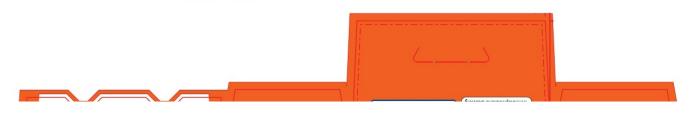
www.StopMedicineAbuse.org

Our Brands, Our Guarantee.

Love It or Your Money Back.

www.kroger.com

## **Packaging**





#### DRUG FACTS TABLE

Active ingredients (in each Softgel) Acetaminophen 325 mg	Purposes reliever / Fever reducer
Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg	reliever / Fever reducer
	Cough suppressant Nasal decongestant
	sore throat fever

#### warnıngs:

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, 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 ■ high blood pressure ■ 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 wyou 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.

## Drug Facts (continued)

#### Directions:

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

at take only to directed 500 overdood warning at the except 4 dood per 24 mo		
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

## KROGER DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-087

Route of Administration ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) **ACETAMINOPHEN** 325 mg **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 10 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** PHENYLEPHRINE HYDROCHLORIDE (UNII: 04|A59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 5 mg UNII:1WS297W6MV) **HYDROCHLORIDE**

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: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142- 087-48	4 in 1 CARTON	08/31/2022	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
1				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/31/2022	

## Labeler - The Kroger Company (006999528)

Revised: 7/2023 The Kroger Company