

KROGER COUGH COLD AND FLU- choline salicylate, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid
THE KROGER CO

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 Cough Cold & Flu

Drug Facts

Active ingredients

(in each 30 mL (2TBSP))

Choline Salicylate (NSAID)* 870 mg

Dextromethorphan HBr 20 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

Temporarily relieves these common cold and flu symptoms:

- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. If changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Salicylates (NSAIDs) may cause a severe allergic reaction which may include:

- hives
- rash
- shock
- skin reddening
- facial swelling
- asthma (wheezing)

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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

- if you have had an allergic reaction to salicylates (including aspirin) or any other pain reliever / fever reducer.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn or if you have ulcers or bleeding problems
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes, or thyroid disease
- you have a cough with excessive phlegm (mucus)
- you have difficulty in urination due to enlargement of the prostate gland
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you have a chronic pulmonary disease or shortness of breath
- you have a sodium restricted diet

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for anticoagulation (thinning the blood) diabetes, gout, or arthritis.
- under a doctor's care for any serious condition
- taking a diuretic

When using this product do not use more than directed**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain, cough, or nasal congestion 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
- ringing in the ears or a loss of hearing occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious

condition.

- nervousness, dizziness, or sleeplessness occurs
- you experience any of the following signs of stomach bleeding
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use salicylates (NSAIDs) during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **Do not exceed recommended dosage.**
- Do not take more than 6 doses in any 24-hour period.
- Use enclosed dose cup
- Keep dosage cup with product
- TBSP=tablespoon
- mL=milliliter
- Adults and children 12 years and over: 30 mL (2 TBSP) every 4 hours
- Children under 12: Do not use

Other information

- each 30 mL (2 TBSP) contains: **Sodium 25 mg**
- tamper evident: Do not use if foil seal under cap is broken or missing.
- read all product information before using
- store at room temperature 68°-86°F (20°-30°C)
- avoid excessive heat and humidity

Inactive ingredients

Edetate sodium, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions or comments?

1-800-632-6900

KROGER COUGH COLD & FLU 8 fl oz (234 mL) Bottle Label



NDC 30142-771-08

FOR AGES 12+

Cough Cold & Flu

DYE-FREE

SUGAR-FREE

Choline Salicylate 870mg - Pain Reliever/
Fever Reducer (**NSAID**)
Dextromethorphan HBr 20mg - Cough Suppressant
Guaifenesin 200mg - Expectorant
Phenylephrine HCl 10mg - Nasal Decongestant

Relieves:

- Aches • Fever • Sore Throat
- Chest Congestion, Cough
- Thins Mucus

Gluten Free
Alcohol Free
Acetaminophen Free



8 FL OZ (237 mL)

Drug Facts

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Drug Facts (continued)

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- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes or thyroid disease
- you have a cough with excessive phlegm (mucus)

Drug Facts (continued)

- you have difficulty in urination due to enlargement of the prostate gland
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you have a chronic pulmonary disease or shortness of breath
- you have a sodium restricted diet

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for anticoagulation (thinning the blood) diabetes, gout, or arthritis.
- under a doctor's care for any serious condition
- taking a diuretic

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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments?

1-800-632-6900

Rev. 09/15

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202

QUALITY GUARANTEE
www.kroger.com

LIFT HERE FOR COMPLETE
DRUG FACT INFORMATION

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QUALITY GUARANTEE
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KEEP LEAFLET AFTER OPENING

KROGER COUGH COLD AND FLU

choline salicylate, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:30 142-771

Route of Administration

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHOLINE SALICYLATE (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-771-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/07/2016	

Labeler - THE KROGER CO (006999528)