

## **KROGER SINUS PAIN AND PRESSURE- choline salicylate, guaifenesin, phenylephrine 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.*

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### **Kroger Sinus Pain & Pressure**

#### ***Drug Facts***

##### ***Active ingredients***

***(in each 30 mL (2 TBSP))***

Choline Salicylate (NSAID)\* 870 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

\*nonsteroidal anti-inflammatory drug

##### ***Purpose***

Pain reliever / fever reducer

Expectorant

Nasal decongestant

##### ***Uses***

Temporarily relieves nasal congestion due to common cold, hay fever and other upper respiratory allergies:

- nasal congestion
- minor aches and pains
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid 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. When using 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 ever had an allergic reaction to salicylates (including aspirin) or 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 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.
- 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 sodium restricted diet
- you have asthma

**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 (NSAID) 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 30mL (2 TBSP) contains: **Sodium 25mg**
- 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 disodium, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol

**Questions or comments?**

**1-800-632-6900**

**KROGER SINUS PAIN & PRESSURE 8 fl oz (237 mL) Bottle Label**

NDC 30142-774-08



FOR AGES 12+

# Sinus Pain & Pressure

**DYE-FREE**

**SUGAR-FREE**

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

Relieves:

- Headache
- Nasal & Chest Congestion
- Sinus Pressure • Thins Mucus

Gluten Free  
Alcohol Free  
Acetaminophen Free



**8 FL OZ (237 mL)**

## Drug Facts

### Active ingredients Purpose (in each 30 mL (2 TBSP))

Choline Salicylate (NSAID)\* 870 mg  
..... Pain reliever /fever reducer  
Guaifenesin 200 mg  
..... Expectorant  
Phenylephrine HCl 10 mg  
..... Nasal decongestant  
\* nonsteroidal anti-inflammatory drug

### Uses

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## Drug Facts (continued)

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- 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

## Drug Facts (continued)

- 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 sodium restricted diet.
- you have asthma

### 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.

## Drug Facts (continued)

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## Drug Facts (continued)

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## Drug Facts (continued)

### Inactive ingredients

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### Questions or comments?

1-800-632-6900

R071415

KEEP LEAFLET AFTER OPENING

LIFT HERE FOR COMPLETE  
DRUG FACT INFORMATION

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Use enclosed dose cup

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

QUALITY GUARANTEE  
www.kroger.com



## KROGER SINUS PAIN AND PRESSURE

choline salicylate, guaifenesin, phenylephrine liquid

### Product Information

#### Product Type

HUMAN OTC DRUG

#### Item Code (Source)

NDC:30 142-774

#### Route of Administration

ORAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
<b>CHOLINE SALICYLATE</b> (UNII: KD510K11QW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:30142-774-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2016	

**Marketing Information**

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

**Labeler** - THE KROGER CO (006999528)

Revised: 6/2016

THE KROGER CO