KROGER NITETIME COLD AND FLU- choline salicylate, diphenhydramine hydrochloride, 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 NiteTIme Cold & Flu

Drug Facts

Active ingredients

(in each 30 mL (2 TBSP))

Choline Salicylate (NSAID)* 870 mg

Diphenhydramine HCl 50 mg

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Antihistamine

Nasal decongestant

Uses

Temporarily relieves these common cold and flu symptoms:

- nasal congestion
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- watery eyes
- temporarily reduces fever

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 any other pain reliever / fever reducer.
- with any other drug containing diphenhydramine, even one used on the skin
- 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.
- 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, thyroid disease, or glaucoma
- you have a cough with excessive phlegm (mucus)
- you have difficulty in urination due to enlargement of the prostate gland
- you have breathing problems such as emphysema or chronic bronchitis
- you have persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you have a sodium restricted diet.

Ask a doctor or pharmacist before use if you are

- taking a precription drug for anti-coagulation (thinning the blood), diabetes, gout, or arthritis
- taking a diuretic
- under a doctor's care for any serious condition
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

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

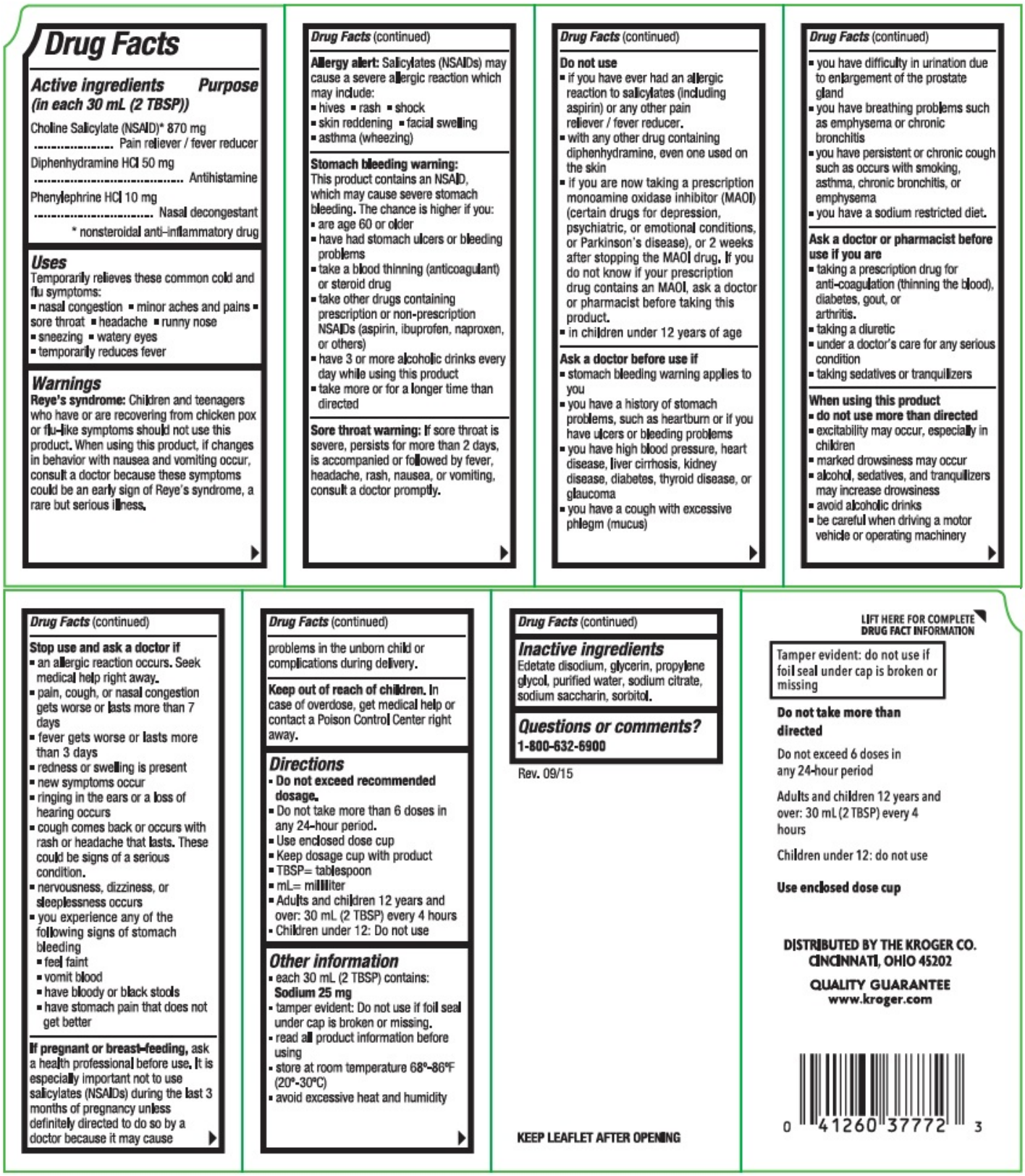
Edetate disodium, glycerin, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions or comments?

1-800-632-6900

Kroger NiteTime Cold & Flu 8 fl oz (237 mL) Bottle Label


NDC 30142-772-08
Kroger
FOR AGES 12+
NiteTime
Cold & Flu
DYE-FREE
SUGAR-FREE
Choline Salicylate 870mg - Pain Reliever/
Fever Reducer (NSAID)
Diphenhydramine HCl 50mg - Antihistamine
Phenylephrine HCl 10mg - Nasal Decongestant
Relieves:
• Aches • Fever • Sore Throat
• Nasal Congestion
• Runny Nose
Gluten Free
Alcohol Free
Acetaminophen Free
Our Pharmacists Recommend
8 FL OZ (237 mL)



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Drug Facts (continued)

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Rev. 09/15

KEEP LEAFLET AFTER OPENING

LIFT HERE FOR COMPLETE DRUG FACT INFORMATION

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CINCINNATI, OHIO 45202

QUALITY GUARANTEE
www.kroger.com

0 41260 37772 3

KROGER NITETIME COLD AND FLU

choline salicylate, diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-772
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL
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

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:30142-772-08	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)

Revised: 6/2016 THE KROGER CO