

SINUS AND COLD D- naproxen sodium, pseudoephedrine hcl tablet, film coated
Kroger Company

Kroger Co. Sinus & Cold-D Drug Facts

Active ingredients (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

Pseudoephedrine HCl 120 mg, extended-release

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Nasal decongestant

Uses

temporarily relieves these cold, sinus, and flu symptoms:

- sinus pressure
- minor body aches and pains
- headache
- nasal and sinus congestion (promotes sinus drainage and restores freer breathing through the nose)
- fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

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

If an allergic reaction occurs, stop use and seek medical help right away.

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 nonprescription 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- 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.
- in children under 12 years of age

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have
- asthma
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- 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
- redness or swelling is present in the painful area
- any new symptoms appear
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing or the caplet feels stuck in your throat

- you get nervous, dizzy, or sleepless
- nasal congestion lasts more than 7 days

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use naproxen sodium 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. (1-800-222-1222)

Directions

- do not take more than directed
- the smallest effective dose should be used
- swallow whole; do not crush or chew
- drink a full glass of water with each dose
- adults and children 12 years and older: 1 caplet every 12 hours; do not take more than 2 caplets in 24 hours
- children under 12 years: do not use

Other information

- each caplet contains: sodium 22 mg
- store at 20-25°C (68-77°F)
- store in a dry place

Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, talc, titanium dioxide

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO active ingredients of ALEVE-D® SINUS & COLD

See side panel

Non-Drowsy

Sinus & Cold-D

Naproxen Sodium 220 mg and Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablet

Pain Reliever/Fever Reducer (NSAID)

Nasal Decongestant

1 Caplet every 12 Hours

12 Hour Multi-Symptom Relief of

Sinus Pressure

Headache

Sinus Congestion

Nasal Congestion

Body Aches

Gluten Free

Actual Size

20 CAPLETS**

**Capsule-Shaped Tablets



Non-Drowsy Sinus & Cold-D

Naproxen Sodium 220 mg and Pseudoephedrine Hydrochloride
120 mg Extended-Release Tablet

**Pain Reliever/Fever Reducer (NSAID)
Nasal Decongestant**

COMPARE TO active ingredients of **ALEVE-D®**
SINUS & COLD ***See side panel

NDC 30142-417-01



Non-Drowsy

Sinus & Cold-D

Naproxen Sodium 220 mg and
Pseudoephedrine Hydrochloride
120 mg Extended-Release Tablet

**Pain Reliever/Fever Reducer (NSAID)
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12 Hour Multi-Symptom Relief of

- ▶ Sinus Pressure
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- ▶ Gluten Free

1 Caplet
every 12 Hours



Actual
Size

**Our
Pharmacists
Recommend**

20 CAPLETS** **Capsule-Shaped Tablets

Do not use if blister unit is broken or torn.
***Aleve-D® Sinus & Cold is a registered trademark of Bayer Healthcare LLC, Pittsburgh, PA 15205.
Bayer Healthcare LLC is not affiliated with The Kroger Co. or this product.

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GLUTEN FREE

Distributed by
The Kroger Co.
Cincinnati, Ohio
45202

QUALITY GUARANTEED

If you are not completely
satisfied with this product, return
it for a refund or replacement.

Comments or questions?

www.Kroger.com

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Drug Facts (continued)

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Drug Facts (continued)**Stop use and ask a doctor if**

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SINUS AND COLD D

naproxen sodium, pseudoephedrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-417
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:5Y76R9ATQ)	NAPROXEN SODIUM	220 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6IU)	

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

POVIDONES (UNII: FZ989GH94E)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	L417
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-417-01	2 in 1 CARTON		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076518	08/21/2013	

Labeler - Kroger Company (006999528)

Revised: 9/2013

Kroger Company