

TOPCARE SINUS AND COLD D- naproxen sodium, pseudoephedrine hcl tablet, film coated, extended release
Topco Associates LLC

Topco Associates LLC. 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

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

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
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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 at 20 weeks or later in 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 21 mg
- meets USP Dissolution Test 2
- 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?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO ALEVE-D® SINUS & COLD

ACTIVE INGREDIENTS

NON-DROWSY

Sinus & Cold-D

NAPROXEN SODIUM 220 mg

PSEUDOEPHEDRINE HYDROCHLORIDE 120 mg

EXTENDED-RELEASE TABLET

PAIN RELIEVER/FEVER REDUCER (NSAID)

NASAL DECONGESTANT

12 HOUR

MULTI-SYMPTOM RELIEF OF:

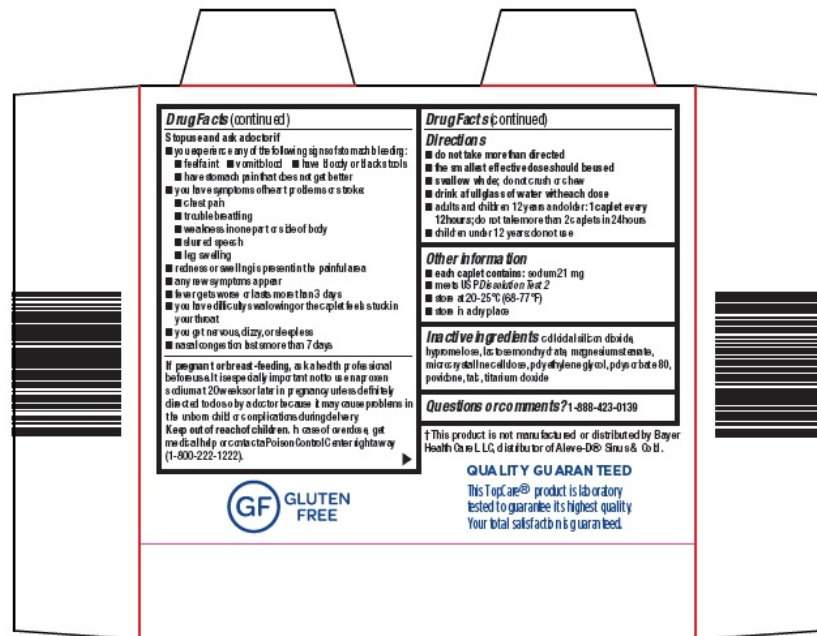
- Sinus Pressure
- Nasal Congestion
- Headache
- Body Aches
- Sinus Congestion

1 Caplet – 12 Hours

20 CAPLETS**

**CAPSULE-SHAPED TABLETS

actual size



Drug Facts		Drug Facts (continued)
Active Ingredients (In each caplet) Naproxen sodium 220 mg (naproxen 200mg) (NSAID)* Pseudoephedrine HCl 120mg, extended-release *nonsteroidal anti-inflammatory drug		Purpose(s) Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. This can be fatal. The risk is higher if you use more than directed or for longer than directed. Directions If you have ever had an allergic reaction to any other pain reliever/fever reducer If you are now taking a prescription monoamine oxidase inhibitor (MAOI) or 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 drugs contain an MAOI, ask a doctor or pharmacist before taking this product. If in child or under 12 years of age
Uses To temporarily relieve the following cold, sinus, and flu symptoms: ■ sinus pressure ■ minor body aches and pains ■ headache ■ nasal and sinus congestion (from colds, sinus, and allergies) and breathing through the nose ■ fever		Warnings Allergy alert: Naproxen sodium may cause severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ difficulty breathing ■ 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 serious stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinner (not just aspirin) or a blood drug ■ take other drugs, including prescription naproxen or aspirin, NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have for more than 10 days every day while using this product ■ take more or for a longer time than directed
When using this product ■ take with food or milk if stomach upset occurs		Ask a doctor or pharmacist before use if: ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver or kidney disease, asthma, thyroid disease, diabetes, have trouble urinating, or are on long-term treatment for high blood pressure ■ you are taking other drugs ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because naproxen may decrease this benefit as aspirin ■ taking any other drug

TOPCARE SINUS AND COLD D			
naproxen sodium, pseudoephedrine hcl tablet, film coated, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-417
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)			NAPROXEN SODIUM	220 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)			PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg
Inactive Ingredients				
Ingredient Name				Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	L417	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-417-52	10 in 1 CARTON	08/14/2013	03/20/2018
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-417-01	20 in 1 CARTON	08/14/2013	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA076518		08/14/2013	

Labeler - Topco Associates LLC (006935977)

