

ALEVE-D SINUS AND HEADACHE- naproxen sodium, pseudoephedrine hydrochloride tablet
Bayer HealthCare LLC.

Aleve-D Sinus & Headache

Drug Facts

Active ingredients

(in each caplet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

Pseudoephedrine HCl 120 mg,

*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, or 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 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 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 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

Other information

- **each caplet contains**: sodium 21 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?

1-800-986-0369

(Mon – Fri 9AM – 5PM EST)

See New Warnings

NON-DROWSY

ALL DAY STRONG®

ALEVE-D®

SINUS & HEADACHE

Naproxen sodium 220 mg (NSAID)

Pseudoephedrine HCl 120 mg extended-release tablets

Pain reliever-fever reducer/nasal decongestant

12 HOUR MULTI-SYMPTOM RELIEF OF

SINUS PRESSURE

HEADACHE · SINUS CONGESTION

NASAL CONGESTION

actual size

1 CAPLET - 12 HOURS

10 CAPLETS

CAPSULE-SHAPED TABLETS

ALL DAY STRONG
ALEVE-D
SINUS & HEADACHE

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ALEVE-D

SINUS & HEADACHE

*Naproxen sodium 220 mg (NSAID)
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12 HOUR MULTI-SYMPTOM RELIEF OF

**SINUS PRESSURE
HEADACHE • SINUS CONGESTION
NASAL CONGESTION**



LOT / EXP AREA

See New Warnings **NON-DROWSY**

Drug Facts

Active ingredients (in each caplet)
Naproxen sodium 220 mg (NSAID)
Pseudoephedrine HCl 120 mg extended-release tablet
Pain reliever-fever reducer/nasal decongestant

Uses temporarily relieves these cold, flu, and flu symptoms:
● sinus pressure ● minor body aches and pains
● headache ● nasal and sinus congestion (congestion)
● sneezing and runny nose
● sore throat and throat irritation (through the nose)

Warnings 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 aspirin 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
● if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychotics, or emetrol 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, kidney disease, asthma, thyroid disease, diabetes, liver cirrhosis, or 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
● you are taking a diuretic

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

Drug Facts (continued)
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.

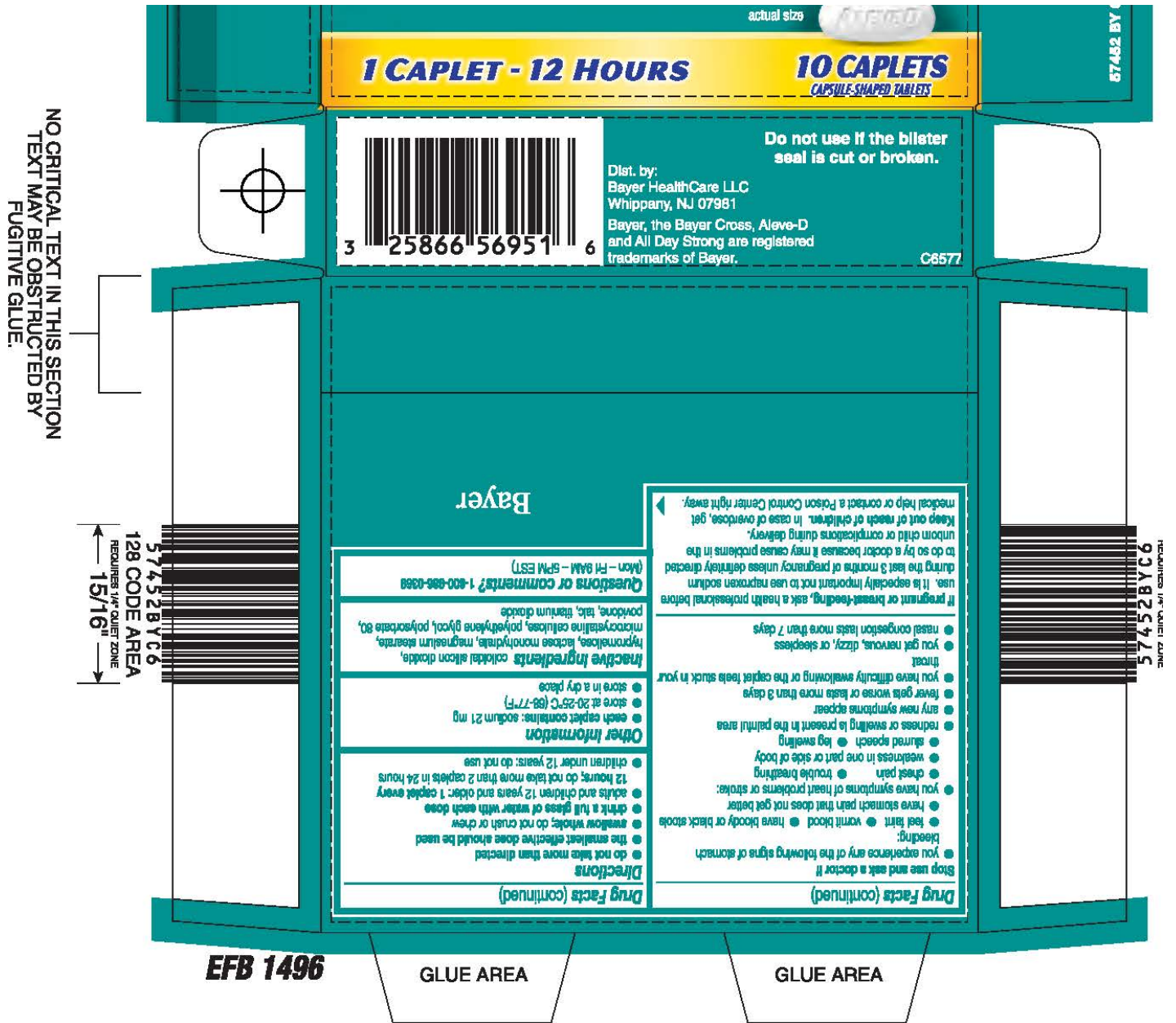
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LIFT HERE **LIFT HERE**



ALEVE-D SINUS AND HEADACHE

naproxen sodium, pseudoephedrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-6045
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Oblong)	Size	17mm
Flavor		Imprint Code	Aleve;D
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-6045-10	1 in 1 CARTON	01/01/2014	
1		10 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	01/01/2014	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2019

Bayer HealthCare LLC.