

**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

**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.
- 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 any other drug

**When using this product**

- take with food or milk if stomach upset occurs

**Drug Facts**

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

**Purposes**  
Nonsteroidal anti-inflammatory drug  
Nasal decongestant

**Uses**  
temporarily relieves these cold, sinus, and flu symptoms:  
● minor body aches and pains  
● sinus pressure  
● nasal and sinus congestion (prolonged drainage and reduces their breathing through the nose)

**Warnings**  
Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
● asthma (wheezing)  
● facial swelling  
● hives  
● rash  
● skin reddening  
● shock  
● stomach bleeding  
● 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

**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  
● are age 60 or older  
Stomach bleeding warning applies to you

**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

**LIFT HERE**

ALL DAY STRONG®  
**ALEVE-D**  
 SINUS & HEADACHE

See New Warnings

NON-DROWSY

ALL DAY STRONG®  
**ALEVE-D**  
 SINUS & HEADACHE

*Naproxen sodium 220 mg (NSAID)  
 Pseudoephedrine HCl 120 mg extended-release tablet  
 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

LOT / EXP AREA

67482 BY C6



3 25866 56951 6

Do not use if the blister seal is cut or broken.

Dist. by:  
 Bayer HealthCare LLC  
 Whippany, NJ 07981

Bayer, the Bayer Cross, Aleve-D  
 and All Day Strong are registered  
 trademarks of Bayer.

C6577

NO CRITICAL TEXT IN THIS SECTION  
 TEXT MAY BE OBSTRUCTED BY  
 FUGITIVE GLUE.

57452BYC6  
 128 CODE AREA  
 REQUIRES 1/4" CLEAR ZONE  
 15/16"

Bayer

**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  
 ● store at 20-25°C (68-77°F)  
 ● store in a dry place

**Inactive ingredients** cickidal silicon dioxide, hydroxyethylcellulose, polyethylene glycol, polyacrylate 80, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-895-0888 (Mon - Fri 9AM - 6PM EST)

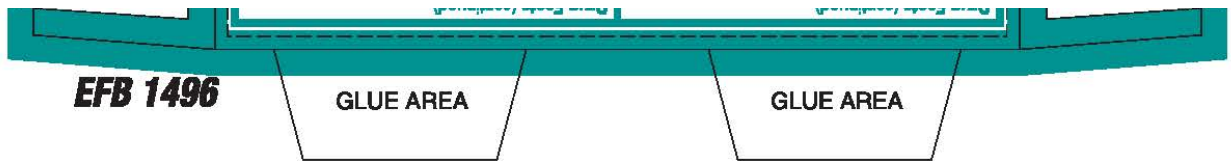
**Stop use and ask a doctor if**  
 ● you experience any of the following signs of stomach bleeding:  
 ● feel faint ● vomit blood ● have bloody or black stools  
 ● have stomach pain that does not get better  
 ● you have symptoms of heart problems or stroke:  
 ● chest pain ● trouble breathing  
 ● weakness in one part or side of body  
 ● blurred 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 feel 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.

57452BYC6

2017 Bayer US Consumer



## ALEVE-D SINUS AND HEADACHE

naproxen sodium, pseudoephedrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-6045
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NAPROXEN SODIUM</b> (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

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

### 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			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076518	01/01/2014	

**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 12/2024

Bayer HealthCare LLC.