

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

Aleve D Sinus and Cold

Drug Facts

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

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

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 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

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
- 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? 1-800-986-0369

Carton 10 count



The Bayer Cross is Less than the "L" in Aleve
 Current Size: 0.409 in
 Current "L" Size: 0.507 in
 Cross Meets Ratio Requirements of 7mm (.2755") or larger
 1/4th of Cross required Clear Space (0.409 in) = 0.102 in
 1/6th of PDP Shortest Side (3.812 in) = 0.635 in

0.162 in 0.507 in
 The "W" in NSAID is Greater than 1/4 of the "L" in ALEVE

| PRE-PRESS | | Client: Bayer HealthCare/USA Consumer Healthcare | | Printing Inks | | Non-Printed Ink | | Color Management | |
|----------------------------|-------------------------------|--|-------------------|-------------------|-------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | Project type: Graphics Change | Brand: Alevin D | Item #: 330010080 | Item #: 330010080 | Item #: 330010080 | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue |
| Job #: 440417 | Version: 2 | Client: Bayer HealthCare/USA Consumer Healthcare | Item #: 330010080 | Item #: 330010080 | Item #: 330010080 | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue |
| Diabetic CSR: CP | Order Date: sd 02-09-20 | Client: Bayer HealthCare/USA Consumer Healthcare | Item #: 330010080 | Item #: 330010080 | Item #: 330010080 | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue |
| Printer: MPS | Printer Location: Holland, MI | Client: Bayer HealthCare/USA Consumer Healthcare | Item #: 330010080 | Item #: 330010080 | Item #: 330010080 | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue |
| All Images/Codes are FINAL | | Client: Bayer HealthCare/USA Consumer Healthcare | Item #: 330010080 | Item #: 330010080 | Item #: 330010080 | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue | Color: PMS Process Blue |

Approved by eary on 17-Feb-2019 19:09

ALEVE-D SINUS AND COLD

naproxen sodium, pseudoephedrine hydrochloride tablet

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0280-6090 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| 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;CS |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:0280-6090-10 | 1 in 1 CARTON | 01/01/2014 | |
| 1 | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0280-6090-20 | 2 in 1 CARTON | 01/01/2014 | |
| 2 | | 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 |
|---------------------------|---|-----------------------------|---------------------------|
|---------------------------|---|-----------------------------|---------------------------|

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|------|------------|------------|--|
| ANDA | ANDA076518 | 01/01/2014 | |
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Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2024

Bayer HealthCare LLC.