ALEVE BACK AND MUSCLE PAIN- naproxen sodium tablet
Bayer HealthCare LLC.

Aleve ® Back and Muscle Pain - Blueshield UI 1614642

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) [1]

1 *nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses
- temporarily relieves minor aches and pains due to:
    - backache
    - muscular aches
    - minor pain of arthritis
    - menstrual cramps
    - headache
    - toothache
    - the common cold

- temporarily reduces 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

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, 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 conidtion
- 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

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a healthcare 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 un 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**
- drink a full glass of water with each dose

Adults and children 12 years and older	- take 1 caplet every 8 to 12 hours while symptoms last - for the first dose you may take 2 caplets within the first hour - do not exceed 2 caplets in any 8- to 12-hour period - do not exceed 3 caplets in a 24-hour period
Children under 12 years	ask a doctor

Other information
- **each caplet contains:** sodium 21 mg
- store at 20-25 ° C (68-77 ° F). Avoid high humidity and excessive heat above 40 ° C (104 ° F).

Inactive ingredients

colloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

PRINCIPAL DISPLAY PANEL

Carton Label

ALL DAY STRONG®

ALEVE®

BACK & MUSCLE PAIN

89135621

ALL DAY STRONG®

ALEVE®

BACK & MUSCLE PAIN

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of minor back and muscle aches and pains

BAYER

ALEVE
ACTUAL SIZE

STRENGTH TO LAST 12 HOURS

50 TABLETS

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981
Bayer
LOT
EXP   MADE IN

0   25866 59203   2

5621   QUIET ZONE   QUIET ZONE

Drug Facts

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(naproxen 200 mg) (NSAID)*.... Pain reliever/
fever reducer
*nonsteroidal anti-inflammatory drug

Uses
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  - the common cold
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- have 3 or more alcoholic drinks every day while using this product
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Drug Facts (continued)

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Do not use
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
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Drug Facts (continued)

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for the first dose you may take 2 tablets within the first hour
do not exceed 2 tablets in any 8- to 12-hour period
do not exceed 3 tablets in a 24-hour period |
| Children under 12 years | ask a doctor |

Other information
- each tablet contains: sodium 21 mg
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Inactive ingredients colloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM – 5PM EST)

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

Do not use if carton is open or if foil seal imprinted with "Bayer HealthCare" on bottle opening is missing or broken.

ALEVE BACK AND MUSCLE PAIN

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0111
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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM CARBOXYMETHYL STARCH (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (capsule shaped tablets)	**Size**	12mm
Flavor		**Imprint Code**	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0111-01	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2024	
2	NDC:0280-0111-02	1 in 1 CARTON	03/25/2024	
2		110 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0280-0111-03	1 in 1 CARTON	03/25/2024	
3		200 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280-0111-04	1 in 1 CARTON	03/25/2024	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0280-0111-05	1 in 1 CARTON	03/25/2024	
5		250 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0280-0111-06	1 in 1 CARTON	03/25/2024	
6		50 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0280-0111-07	1 in 1 CARTON	03/25/2024	
7		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

| NDA | NDA020204 | 04/04/2023 | |

Revised: 4/2025   Bayer HealthCare LLC.