

**ALEVE HEADACHE PAIN- naproxen sodium tablet**  
**Bayer HealthCare LLC**

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**Aleve ® Headache Pain**

**Active Ingredient**

Naproxen Sodium 220mg

**Purposes:**

Pain reliever/fever reducer

**Uses:**

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

**Ask a Doctor:**

- 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**

- 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**

- 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

### **The pregnancy/breast-feeding warning:**

**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:**

**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

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Adults and children 12 years and older	<ul style="list-style-type: none"><li>• take 1 tablet every 8 to 12 hours while symptoms last</li><li>• for the first dose you may take 2 tablets within the first hour</li><li>• do not exceed 2 tablets in any 8- to 12-hour period</li><li>• do not exceed 3 tablets in a 24-hour period</li></ul>
Children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

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### **Other information:**

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

### **Inactive ingredient**

FD&C BLUE #2 LAKE, HYPROMELLOSE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL, POVIDONE, TALC, TITANIUM DIOXIDE

### **Questions & comments:**

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

Dist. by :

Bayer Healthcare LLC

Whippany, NJ 07981

ALL DAY STRONG®

ALEVE

HEADACHE PAIN

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

Bayer

For temporary relief of headache pain

ACTUAL SIZE

STRENGTH TO LAST 12 HOURS

TABLETS



**ALEVE HEADACHE PAIN**

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-0041
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>2-NAPHTHALENEACETIC ACID, 6-METHOXY-.ALPHA.-METHYL-, SODIUM SALT, (S)-</b> (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	2-NAPHTHALENEACETIC ACID, 6-METHOXY-.ALPHA.-METHYL-, SODIUM SALT, (S)-	220 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	ALEVE
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0041-01	1 in 1 CARTON	06/01/2021	
1		175 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0280-0041-02	1 in 1 CARTON	06/01/2021	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0280-0041-04	1 in 1 CARTON	06/01/2021	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280-0041-03	1 in 1 CARTON	06/01/2021	
4		90 in 1 BOTTLE; Type 0: Not a Combination		

4		Product	
5	NDC:0280-0041-05	1 in 1 POUCH; Type 0: Not a Combination Product	06/01/2021



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	06/01/2021	

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

Revised: 6/2021

Bayer HealthCare LLC