

BAYER ALEVE- naproxen sodium tablet
Unifirst First Aid Corporation

Bayer Aleve

Drug Facts

Active ingredient (in each caplet)

Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - 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 stomach ulcers or bleeding problems
- take a blood thinner (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:

NSAID,s 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 ever have had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- 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 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
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for 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 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 accidental 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 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients

FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?

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

All Day Strong[®]

Aleve[®]

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

Bayer

Pull To Open

Strength To Last 12 Hours

50 Caplets

Capsule-Shaped Tablets

Drug Facts

Active ingredient (in each caplet)
Naproxen sodium 220 mg (naproxen 110 mg) (NSAID)
Nonsteroidal anti-inflammatory drug

Purposes
Pain reliever/fever reducer

Uses

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

Warnings

Alergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives; facial swelling; asthma (breathing); dizziness; skin redness; 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 problems, kidney disease, asthma, or had a stroke
- you are taking aspirin
- 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

Put to Open

Drug Facts (continued)

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:
 - fast food
 - stomach pain
 - 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 looks like the pill is stuck in part of throat
- redness or swelling is present in it in the painful area
- any new symptoms appear

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
- 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 best effect you may take 2 caplets with the first hour
- do not exceed 3 caplets in any 8- to 12-hour period
- do not exceed 2 caplets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

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

Inactive ingredients
FD&C Blue #2 Ink, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydimethylsiloxane, talc, titanium dioxide

Questions or comments?
1-800-368-0888 (Use-Fix-SAM - 5PM EST)

Retain carton for complete product information

Retain carton for complete product information

Retain carton for complete product information

BAYER ALEVE

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-488
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:5Y76R9ATQ)	NAPROXEN SODIUM	220 mg	

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

Product Characteristics			
Color	blue (blue)	Score	no score
Shape	OVAL (OVAL)	Size	14mm
Flavor		Imprint Code	ALEVE
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:47682-488-50	50 in 1 BOX	01/24/2014	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	01/24/2014	

Labeler - Unifirst First Aid Corporation (832947092)

Registrant - Unifirst First Aid Corporation (832947092)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer Healthcare LLC		072827066	manufacture(47682-488)

Establishment

Name	Address	ID/FEI	Business Operations
Medique Products		086911794	repack(47682-488)

Revised: 4/2019

Unifirst First Aid Corporation