

BAYER ALEVE- naproxen sodium tablet
Acme United 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 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: NSAID,s except aspirin, increase the risk of heart attack, heart failure and stroke. These can be fatal. This 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

- 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 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

- 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 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)

Box Label

ALL DAY STRONG®
ALEVE®
 naproxen sodium tablets, 220 mg (NSAID)
 Pain reliever/fever reducer

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Drug Facts (continued)	
<p>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.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose 	
<p>Adults and children 12 years and older</p> <ul style="list-style-type: none"> 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 	<p>Children under 12 years</p> <ul style="list-style-type: none"> ask a doctor
<p>Other information</p> <ul style="list-style-type: none"> 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). 	
<p>Inactive ingredients</p> <p>FD&C Blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide</p>	
<p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p>	



Tamper-Resistant Packets of 1 Caplet
 Do not use if packet is open or torn.



STRENGTH TO LAST 12 HOURS

50 CAPLETS
 (50 Packets, 1 caplet each)

Drug Facts		Drug Facts (continued)
<p>Active ingredient (in each caplet)</p> <p>Naproxen sodium 220 mg (naproxen 200 mg) (NSAID).....Pain reliever/fever reducer</p> <p><i>*nonsteroidal anti-inflammatory drug</i></p>	<p>Purposes</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> minor pain of arthritis muscular aches backache menstrual cramps headache toothache the common cold temporarily reduces fever 	<p>Do not use</p> <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery
<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> minor pain of arthritis muscular aches backache menstrual cramps headache toothache the common cold temporarily reduces fever 	<p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives facial swelling asthma (wheezing) shock skin reddening rash blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> 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 <p>Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. This risk is higher if you use more than directed or for longer than directed.</p>	<p>Ask a doctor before use if</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> 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 <p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools vomit blood have stomach pain that does not get better you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> chest pain trouble breathing slurred speech leg swelling weakness in one part or side of body pain gets worse or lasts more than 10 days fever gets worse or last 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

BAYER ALEVE

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-6000(NDC:0280-6000)
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
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
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Shape	OVAL (OVAL)	Size	12mm
Flavor		Imprint Code	Aleve
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-6000-01	50 in 1 BOX	03/24/2023	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0924-6000-00	1 in 1 POUCH; Type 0: Not a Combination Product	03/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	03/24/2023	

Labeler - Acme United Corporation (001180207)

Registrant - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-6000) , repack(0924-6000)

Revised: 3/2023

Acme United Corporation