

ALL DAY PAIN RELIEF- naproxen sodium tablet
P & L Development, LLC

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 USP, mg (naproxen 200 mg) (NSAID)*

*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

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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- 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 have problems or serious side effects from taking pain relievers or fever reducers you are taking a diuretic
- you are taking a diuretic

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:
 - have bloody or black stools
 - feel faint
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problem or stroke:
 - 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 lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing

- it feels like the pill is stuck in your throat

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 (1-800-222-1222) right away.

Directions

- **do not make 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 tablet every 8 to 12 hours while symptoms last
 - for the first dose you may take 2 tablets within the first hour
 - do not exceed 2 tablets in a 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 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients

croscarmellose sodium, FD&C blue # 2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in **Aleve**®†

All Day Pain Relief

Naproxen sodium tablets,

(NSAID) 220 mg

pain reliever/fever reducer

strength to last 12 hours

Tablets

†This product is not manufactured or distributed by Bayer Healthcare, LLC, distributor Aleve®.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

**TAMPER EVIDENT:DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT
INFORMATION.**

Package Labeling

Drug Facts (continued)

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 (1-800-222-1222) 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 tablet every 8 to 12 hours while symptoms last
 - 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 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments?
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Aleve®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



Compare to the active ingredient in Aleve®†
NDC 59726-169-40

all day
pain relief

naproxen sodium tablets,
(NSAID) 220 mg

pain reliever/fever reducer
strength to last 12 hours

40 tablets



Drug Facts

Active ingredient (in each tablet)	Purposes
Naproxen sodium USP, 220 mg	Pain reliever/fever reducer
(naproxen 200 mg) (NSAID)*	fever reducer
*nonsteroidal anti-inflammatory drug	

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

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.

Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590



3 59726 16940 0

PLD-A1161
FC008136

Lot No.:
Exp. Date:

READYinCASE All Day Pain Relief

ALL DAY PAIN RELIEF			
naproxen sodium tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-169
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		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	I3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-169-15	1 in 1 BOX	02/28/2014	
1		15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-169-40	1 in 1 BOX	02/28/2014	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	02/28/2014	

Labeler - P & L Development, LLC (800014821)

Revised: 2/2022

P & L Development, LLC