### NAPROXEN SODIUM- naproxen sodium tablet Walgreens

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**Drug Facts** 

Active ingredient (in each capsule)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)\*

\*nons teroidal anti-inflammatory drug

### **Purposes**

Pain reliever/fever reducer

### Uses

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

### 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
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problem or stroke:
  - chest pain
  - slurred speech
  - leg swelling
  - trouble breathing
  - weakness in one part or side of the 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 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
  - o 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)
- read all warnings and directions before use. Keep carton.
- swallow whole: do not crush, chew or dissolve

### **Inactive ingredients**

FD&C blue #1, gelatin, glycerin, lactic acid, polyethylene glycol, sorbitan, sorbitol, white pharmaceutical ink

### Questions or comments?

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

### **Principal Display Panel**

Compare to Aleve® Liquid Gels active ingredient††

Naproxen Sodium

CAPSULES, 220 mg (NSAID) / PAIN RELIEVER / FEVER REDUCER

12 HOURS LIQUID GELS

LIQUID GELS\*\*

(\*\*LIQUID-FILLED CAPSULES)

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

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

### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

### **Package Label**

Lot No.:

PLD-A530A FC006802



DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

# Drug Facts (continued)

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

Pain reliever/ fever reducer

Vaproxen sodium 220 mg Active ingredient (in each capsule)

**Drug Facts** 

## 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 any other drug

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms

When using this product, take with food or milk if stomach upset

# you experience any of the following signs of stomach bleeding Stop use and ask a doctor if

- have bloody or black stools feel faint womit blood
- have stomach pain that does not get better
- weakness in one part or side of the body ■ leg swelling ■ trouble breathing slurred speech chest pain

you have symptoms of heart problems or stroke:

which may cause severe stomach bleeding. The chance is higher if

Stomach bleeding warning: This product contains an NSAID

if an allergic reaction occurs, stop use and seek medical help right

■ facial swelling ■ asthma (wheezing)
■ skin reddening ■ rash ■ blisters

■ hives shock

- 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 capsule is stuck in your throat

by a doctor because it may cause problems in the unborn child or the last 3 months of pregnancy unless definitely directed to do so use. It is especially important not to use naproxen sodium during If pregnant or breast-feeding, ask a health professional before complications during delivery.

# Drug Facts (continued)

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 a do not take more than directe the smallest effective dose should be used

- If taken with food, this product may take longer to work drink a full glass of water with each dose
- take 1 capsule every 8 to 12 hours while symptoms last adults and children 12 years and older:
- for the first dose you may take 2 capsules within the first hour do not exceed 2 capsules in any 8- to 12-hour period
  - - I do not exceed 3 capsules in a 24-hour period children under 12 years: ask a doctor

# Other information

■ store at 20 to 25°C (68 to 77°F), excursions permitted between each capsule contains: sodium 20 mg

emperature]. Avoid high humidity and excessive heat above 15°C and 30°C (59°F to 86°F) [See USP Controlled Room 40°C (104°F

 read all directions and warnings before use. Keep carton. swallow whole; do not crush, chew, or dissolve

pharmaceutical ink (ammonium hydroxide, polyethylene glycol polyvinyl acetate phthalate, propylene glycol, titanium dioxide) Inactive ingredients FD&C blue #1, gelatin, glycerin, actic acid, polyethylene glycol, sorbitan, sorbitol, white

# Questions or comments?

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

TAMPER EVIDENT: DO NOT USE IF PRINTED Safety seal under cap is broken or missing

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

PLASTIC BOTTLE

BOX

Walgreens

temporarily relieves minor aches and pains due to:

minor pain of arthritis

backache I headache

 menstrual cramps muscular aches

toothache

temporarily reduces fever

The common cold

Compare to Aleve® Liquid Gels active ingredient<sup>††</sup>

 take other drugs containing prescription or nonprescription have 3 or more alcoholic drinks every day while using this

NSAIDs (aspirin, ibuprofen, naproxen, or others)

take more or for a longer time than directed

take a blood thinning (anticoagulant) or steroid drug

have had stomach ulcers or bleeding problems

are age 60 or older

NDC 0363-7510-40

**ACTUAL SIZE** 

can be fatal. The risk is higher if you use more than directed or for Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These

onger than directed

### proxen Sodiu

CAPSULES, 220 mg (NSAID) / PAIN RELIEVER / FEVER REDUCER

HOUR

LIQUID GELS

LIQUID GELS\*\* (\*\*LIQUID-FILLED CAPSULES)

### WALGREENS Naproxen Sodium 220 mg Capsules

### NAPROXEN SODIUM

naproxen sodium tablet

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-7510

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. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
LACTIC ACID (UNII: 33X04XA5AT)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
SORBITAN (UNII: 6O92ICV9RU)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL	Size	20 mm	
Flavor		Imprint Code	NP220	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7510- 40	1 in 1 BOX	0 1/3 1/2 0 2 0	
1		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0363-7510- 80	1 in 1 BOX	0 1/3 1/2 0 2 0	
2		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0363-7510- 20	1 in 1 BOX	0 1/3 1/2 0 2 0	
3		20 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	ANDA202807	01/31/2020		

### Labeler - Walgreens (008965063)

Revised: 4/2020 Walgreens