

NAPROXEN SODIUM- naproxen sodium tablet

Family Dollar (FAMILY WELLNESS)

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:
 - 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
 - trouble breathing
 - 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 right away (1-800-222-1222).

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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD&C blue #2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

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

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT OF ALEVE®†

SEE NEW WARNINGS

STRENGTH TO LAST 12 HOURS

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever / Fever Reducer **(NSAID)**

CAPLETS**

(**CAPSULE-SHAPED TABLETS)

†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

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

10611 MONROE RD., MATTHEWS, NC 28105

Product Label

<p><i>Drug Facts (continued)</i></p> <p>directed or for longer than directed.</p> <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>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 have problems or serious side effects from taking pain relievers or fever reducers ■ you are taking a diuretic 	<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 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"> ■ have bloody or black stools ■ feel faint ■ 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 ■ slurred speech ■ trouble breathing ■ 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 ■ you have new symptoms appear ■ you have difficulty swallowing ■ it feels like the pill is stuck in your throat
<p><i>Drug Facts (continued)</i></p> <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 (1-800-222-1222).</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 ■ adults and children 12 years and older: <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 ■ children under 12 years: ask a doctor 	<p>Other information</p> <ul style="list-style-type: none"> ■ each caplet contains: sodium 20 mg ■ store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40° (104°F). 	<p>Inactive ingredients FD&C blue #2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone K-30, sodium carboxylate, stearic acid, titanium dioxide</p>	<p>Questions or comments? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST</p>	

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

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COMPARE TO THE ACTIVE INGREDIENT OF ALEVE®†

SEE NEW WARNINGS

STRENGTH TO LAST 12 HOURS

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg
Pain Reliever/Fever Reducer (**NSAID**)

24 CAPLETS**
(**CAPSULE-SHAPED TABLETS)

ACTUAL SIZE

FAMILY **wellness**™

100% SATISFACTION
OR YOUR MONEY BACK
GUARANTEED

OTC
network

FAMILY WELLNESS All Day Pain Relief Caplets

Route of Administration

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)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	220
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-255-01	1 in 1 BOX	04/30/2014	04/26/2024
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55319-255-24	1 in 1 BOX	04/30/2014	04/26/2024
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:55319-255-50	1 in 1 BOX	04/30/2014	04/26/2024
3		50 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	ANDA091353	04/30/2014	04/26/2024

Revised: 10/2021

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