

**NAPROXEN SODIUM - naproxen sodium tablet, film coated
WALMART INC.**

Naproxen Sodium Tablets, USP 220 mg

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium USP 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
- menstrual cramps
- toothache
- backache
- headache
- 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.

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 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 more than 10 days
- fever gets worse or lasts 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 at 20 weeks or later in 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	<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	<ul style="list-style-type: none"> • 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

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

Questions or comments?

1-888-287-1915

DISTRIBUTED BY:

**Walmart Inc.,
Bentonville, AR 72716**

PRODUCT OF INDIA

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

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (50 Tablets Bottle)

NDC 79903-231-50

**equate™
All Day Pain Relief**

**Naproxen Sodium
Tablets USP, 220 mg
(NSAID)**

**Pain Reliever/
Fever Reducer
Strength to Last 12 Hours**

**12
HOURS**

**220
mg**

**50
CAPLETS†
†Capsule-Shaped Tablets**

Top Ply

equate™	NDC 79905-251-50	Drug Facts	Purpose(s)	DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.	Lift Here
All Day Pain Relief	12 HOURS	Active ingredient (in each caplet)	Naproxen sodium USP 220 mg (naproxen 200 mg) (NSAID)*	DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716 PRODUCT OF INDIA 535063	
Naproxen Sodium Tablets USP, 220 mg (NSAID)	220 mg 50 CAPLETS	*nonsteroidal anti-inflammatory drug	Uses ■ temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ muscular aches ■ backache ■ headache ■ the common cold ■ menstrual cramps ■ toothache	P1433823 LM-5509	
Pain Reliever/ Fever Reducer Strength to Last 12 Hours	Comb-shaped tablets	Warnings ■ temporarily reduces fever	Allergy alert: Naproxen sodium may cause a severe allergic	* Unvarnished Zone (dotted line not for printing) 34 x 12.5 mm	

A/s: 1 x 4.25 Inch

Black



SCD

Date: 12.10.2023 & 03.10 PM

Version: 1

Top Ply
(Page #1)

*Lot: XXXXXXXXX
 Exp.: YYYY-MMM
 Prefix, Variables of Lot, Exp and Neutral code shall be printed online during packing.

Drug Facts (continued)	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. 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 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	HINGE
	P1433823 LM-5509	

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Bottom Ply

HINGE	Drug Facts (continued)	■ 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 more than 10 days ■ fever gets worse or lasts 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 at 20 weeks or later in 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 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 colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, and titanium dioxide
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Base
(Page #3)
Bottom Ply

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (50 Tablets Carton Label)

**NDC 79903-231-50
equate™**

**Compare
to Aleve®
caplets
active
ingredient****

**All Day
Pain Relief**

**Naproxen Sodium
Tablets USP, 220 mg
(NSAID)**

***Pain Reliever/
Fever Reducer
Strength to
Last 12 Hours***

**12
HOURS**

**220 50
mg CAPLETS†
EACH**

Actual Size

†Capsule-Shaped Tablets



NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79903-231
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

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	K;45
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-231-50	1 in 1 CARTON	02/14/2024	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205497	02/14/2024	

Labeler - WALMART INC. (051957769)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(79903-231) , MANUFACTURE(79903-231)

Revised: 4/2024

WALMART INC.