# AMAZON BASIC CARE NAPROXEN SODIUM - naproxen sodium tablet, film coated

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# Naproxen Sodium Tablets, USP 220 mg *Drug Facts*

## Active ingredient (in each tablet)

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:
- headache
- minor pain of arthritis
- muscular aches
- backache
- menstrual cramps
- 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.

#### 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

12 years and older	<ul> <li>take 1 tablet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 tablets within the first hour</li> <li>do not exceed 2 tablets in any 8 to 12 hour period</li> <li>do not exceed 3 tablets in a 24 hour period</li> </ul>
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).

# 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?

1-855-274-4122

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Made in India

\*\*\*This product is not Manufactured or distributed by Bayer Healthcare LLC, distributor of Aleve®.

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (90 Tablets, Container Label)

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basic+care

Strength to Last 12 Hours

NDC 72288-366-90

Naproxen Sodium Tablets USP 220 mg (NSAID)

Pain Reliever/Fever Reducer

90 TABLETS



basic \*\* care

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\* temporarily relieves minor aches and pains due to:

■ headache

minor pain of arthritis

muscular aches

■ backache ■ toothache

■ menstrual cramps■ the common cold

temporarily reduces fever

Warnings

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Do not use if seal over bottle opening is broken or missing.

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LM-5715 P1434068

Unvarnished Zone (dotted line not for printing) 30 x 14 mm

#### **Drug Facts** (continued)

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 ingith before or after heart surgery Ask a doctor before use if in the stomach bleeding warning applies to you in 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 in 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 aske 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: In teel faint of you have bloody or black stools. have stomach pain that does not get better you have symptoms of heart problems or stroke: In chest pain to the product of the following signs of stomach bleeding: In teel faint of you have bloody or black stools. have stomach pain that does not get better you have symptoms of heart problems or stroke: In the painful area and not have symptoms of heart problems or stroke: In the painful area and not have 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 ch

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (90 Tablets Container Carton Label)

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Strength to Last 12 Hours

Compare to Aleve® active ingredient\*\*\*

NDC 72288-366-90

Naproxen Sodium

# Tablets USP 220 mg (NSAID)

Pain Reliever/ Fever Reducer

#### 90 TABLETS



#### **AMAZON BASIC CARE NAPROXEN SODIUM**

naproxen sodium tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-366
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	ROUND (Circular)	Size	10mm
Flavor		Imprint Code	J;67
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-366- 90	1 in 1 CARTON	05/15/2024	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72288-366- 20	1 in 1 CARTON	05/15/2024	
2		200 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72288-366- 30	1 in 1 CARTON	05/15/2024	
3		300 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	05/15/2024	

# **Labeler -** Amazon.com Services LLC (128990418)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aurobindo Pharma Limited		650381903	ANALYSIS(72288-366), MANUFACTURE(72288-366)	

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