## NAPROXEN SODIUM- naproxen sodium capsule, liquid filled Amazon.com Services LLC

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# Amazon Basic Care-Naproxen Sodium Casules, 220 mg Drug Facts

## Active ingredients (in each capsule)

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:
  - minor pain of arthritis
  - muscular aches
  - backache
  - 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

#### 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

- 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
- slurred speech
- weakness in one part or side of body
- leg swelling
- 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

### 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 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
- if taken with food, this product may take longer to work

adults and children 12 years and older:	<ul> <li>take 1 capsule every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 capsules within the first hour</li> <li>do not exceed 2 capsules in any 8-to 12-hour period</li> <li>do not exceed 3 capsules in a 24-hour period</li> </ul>
children under 12 years:	ask a doctor

#### Other information

- each capsule contains:sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- protect from light
- read all directions and warnings before use.

## Inactive ingredients

FD&C blue #1, gelatin, glycerin, lactic acid, mannitol, pharmaceutical ink, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

## Questions or comments?

1-888-235-2466 (Mon - Fri 9AM - 5PM EST)

#### PRINCIPAL DISPLAY PANEL - 120's bottle label

Do not use if printed safety seal under cap is torn or missing.

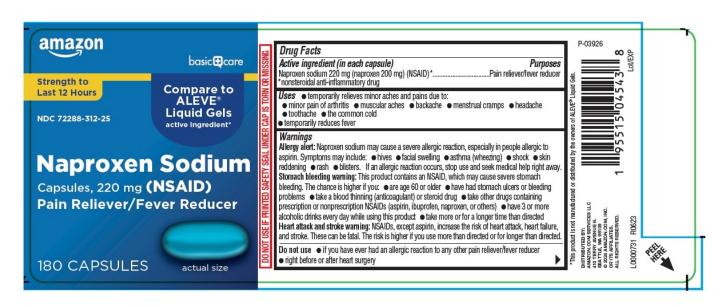
\*\*\*This product is not manufactured or distributed by the owners of ALEVE ® Liquid Gels.

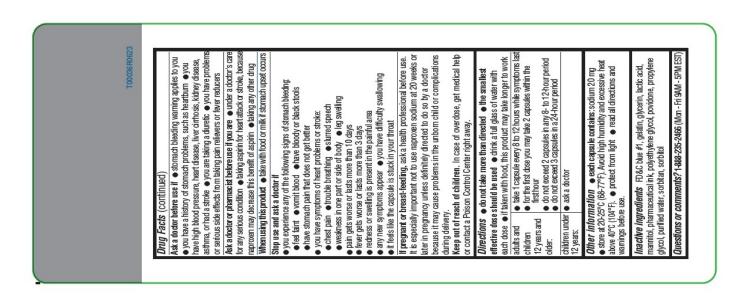
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P-03926

L0000731

R0623 Lot/Exp





#### NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-312	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: PDC6A3C0OX)			
LACTIC ACID (UNII: 33X04XA5AT)			
MANNITOL (UNII: 3OWL53L36A)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE K30 (UNII: U725QWY32X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6092ICV9RU)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics			
Color	blue (Blue with white text)	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	NP1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288- 312-25	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/12/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021920	02/12/2024	

## Registrant - Bionpharma Inc. (079637826)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Patheon Softgels Inc.		002193829	manufacture(72288-312)	

Revised: 2/2024 Amazon.com Services LLC