

NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
Bionpharma Inc.

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

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

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

adults and children 12 years and older:	<ul style="list-style-type: none">• take 1 capsule every 8 to 12 hours while symptoms last• 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• do not exceed 3 capsules in a 24-hour period
children under 12 years:	<ul style="list-style-type: none">• 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)

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.

Manufactured for:

BIONPHARMA

600 Alexander Road,

Princeton, NJ 08540

R1120

L0000392

PRINCIPAL DISPLAY PANEL - 120's bottle label

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-179
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: 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: 6O92ICV9RU)	
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:69452-179-79	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	11/01/2018
2	NDC:69452-179-11	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	11/01/2018
3	NDC:69452-179-15	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	11/01/2018
4	NDC:69452-179-78	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	11/01/2018
5	NDC:69452-179-20	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	11/01/2018
6	NDC:69452-179-22	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021920	11/01/2018	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(69452-179)

Revised: 2/2021

Bionpharma Inc.