NAPROXEN SODIUM- naproxen sodium capsule, liquid filled Rite Aid Corporation

Naproxen Sodium Capsules - Rite Aid

Drug Facts

Active ingredient (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
- 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
- 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:	 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:	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)
- read all directions and warnings before use. Keep carton.

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)

**This product is not manufactured or distributed by the owners of ALEVE $^{\mbox{\scriptsize B}}$ Liquid Gels.

DISTRIBUTED BY: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011 www.riteaid.com SATISFACTION GUARANTEE: If you're not satisfied, we'll happily refund your money. L00005424 R0821 Lot/Exp

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient Of ALEVE [®] Liquid Gels STRENGTH TO LAST 12 HOURS PAIN RELIEVER/ FEVER REDUCER NAPROXEN SODIUM NAPROXEN SODIUM CAPSULES, 220 mg (NSAID) DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS TORN OR MISSING. ACTUAL SIZE 80 CAPSULES



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NAPROXEN S	ODIUM					
naproxen sodium c	apsule, liqu	id filled				
Product Informa	ation					
Product Type		HUMAN OTC DRUG	Item Code (So	urce)	NDC:1182	2-0788
Route of Administ	ration	ORAL				
Active Ingredien	t/Active I	Moiety				
	Ingre	dient Name		Basis of S	Strength	Strength
NAPROXEN SODIUM	UNII: 9TN87S	3A3C) (NAPROXEN - UNII:	57Y76R9ATQ)	NAPROXEN SO	DIUM	220 mg
Inactive Ingredi	ents					
		Ingredient Name			S	trength
FD&C BLUE NO. 1 (UI		BD)				
GELATIN (UNII: 2G86Q						
GLYCERIN (UNII: PDC6	A3C0OX)					
LACTIC ACID (UNII: 33	X04XA5AT)					
MANNITOL (UNII: 30W						
		CIFIED (UNII: 3WJQ0SDW1	.A)			
POVIDONE (UNII: FZ98						
PROPYLENE GLYCOL		167V3)				
WATER (UNII: 059QF0k						
SORBITAN (UNII: 6092						
SORBITOL (UNII: 506T	60A25R)					
Product Charact	oristics					
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	CAPSULE	II WIIILE LEXL)	Score			score
	LAPSULE		Size	Cada	25n	
Flavor			Imprint	Code	NP1	•
Contains						

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822- 0788-4	1 in 1 CARTON	04/15/2020	
1		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11822- 0788-5	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2021	
3	NDC:11822- 0788-6	1 in 1 CARTON	03/01/2023	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Ν	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	A	NDA021920	04/15/2020	

Labeler - Rite Aid Corporation (014578892)

Registrant - Bionpharma Inc. (079637826)

Establishment									
ess ID/FEI	Business Operations								
002193829	manufacture(11822-0788)								
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Revised: 3/2023

Rite Aid Corporation