

NAPROXEN SODIUM- naproxen sodium tablet, film coated
Rite Aid Corporation

Rite Aid 44-604

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - the common cold
 - toothache
 - menstrual cramps
 - backache
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- asthma (wheezing)
- skin reddening
- shock
- blisters
- rash
- facial swelling
- hives

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]

- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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 have problems or serious side effects from taking pain relievers or fever reducers
- you are taking a diuretic

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:
 - leg swelling
 - chest pain
 - slurred speech
 - trouble breathing
 - weakness in one part or side of body
- 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 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°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal display panel

NDC 11822-6040-6

Compare to the
active ingredient of
Aleve® Caplets†

STRENGTH TO LAST 12 HOURS

NAPROXEN
SODIUM

NAPROXEN SODIUM
TABLETS, 220 mg

PAIN RELIEVER/
FEVER REDUCER
(NSAID)

ACTUAL SIZE

200

CAPLETS**

**capsule-shaped tablets

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

†This product is not manufactured or distributed by Bayer HealthCare
LLC, owner of the registered trademark Aleve® Caplets.
50844 REV1221A60415

DISTRIBUTED BY: RITE AID,
200 NEWBERRY COMMONS
ETTERS, PA 17319 **www.riteaid.com**

**SATISFACTION
GUARANTEE**

If you're not satisfied, we'll
happily refund your money.



Rite aid 44-604

NAPROXEN SODIUM			
naproxen sodium tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6040
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
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Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	44;604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6040-6	1 in 1 CARTON	07/18/2022	
1		200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11822-6040-8	1 in 1 CARTON	07/18/2022	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11822-6040-5	1 in 1 CARTON	07/18/2022	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:11822-6040-7	270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2022	
5	NDC:11822-6040-9	1 in 1 CARTON	07/18/2022	
5		90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:11822-6040-2	1 in 1 CARTON	07/18/2022	01/03/2025
6		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	07/18/2022	

Labeler - Rite Aid Corporation (014578892)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(11822-6040)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-6040) , pack(11822-6040)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-6040)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(11822-6040)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-6040)