NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
P & L Development, LLC

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

- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed

Heart attack and stroke: 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
  - leg swelling
  - slurred speech
  - 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
- 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 (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
- 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 between 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. Keep carton.

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitan, sorbitol solution, titanium dioxide, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredient in Aleve® Liquid Gels

all day pain relief

naproxen Sodium

capsules, 220 mg (NSAID)

pain reliever/fever reducer

Strength to lasts 12 hours

liquid gels**

(**liquid-filled capsules)

†This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve®Liquid Gels.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label

ready incase
†Compare to the active ingredient in Aleve® Liquid Gels
NDC 59726-748-80
all day pain relief
naproxen sodium
capsules, 220 mg (NSAID)
pain reliever/fever reducer
strength to last 12 hours
80 liquid gels**
(**liquid-filled capsules)
Drug Facts
Active ingredient (in each capsule) Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug
Uses
■ temporarily relieves minor aches and pains due to:
■ minor pain of arthritis ■ muscular aches
■ backache ■ menstrual cramps
■ headache ■ toothache
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■ 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
Drug Facts (continued)
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
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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.
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Directions ■ do not take more than directed
Drug Facts (continued)
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■ children under 12 years: ask a doctor
Other information
■ each capsule contains: sodium 20 mg
■ store between 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. Keep carton.
Inactive ingredients FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide, white ink
Questions or comments?
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST
†This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve® Liquid Gels.
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590
TRUST QUALITY EXCELLENCE
3 59726 74880 3
PLD-6528E
FC0808024
Lot No.:
Exp. Date:

READYinCASE All day Pain Relief

NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-748
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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
ALCOHOL (UNII: 3K9958V90M)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	PC19
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-748-20	1 in 1 BOX	02/25/2022	02/26/2027

1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59726-748-80	1 in 1 BOX	02/25/2022	02/26/2027
2		80 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	ANDA208363	02/25/2022	02/26/2027

Labeler - P & L Development, LLC (800014821)

Revised: 1/2026 P & L Development, LLC