

NAPROXEN SODIUM- naproxen sodium capsule, liquid filled AAFES/Your Military Exchanges

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 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, or kidney disease
- you have 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 stool
 - 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 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. Keep carton.

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone K30, 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
Naproxen Sodium**

Capsules, 220 mg (NSAID)

Pain Reliever/Fever Reducer

STRENGTH TO LAST 12 HOURS

LIQUID GELS**

(**LIQUID-FILLED CAPSULES)

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

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT
INFORMATION**

Manufactured For Your Military Exchange

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label

*Compare to the active ingredient in Aleve® Liquid Gels

exchange **select™**

Naproxen Sodium

Capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer

STRENGTH TO LAST 12 HOURS



Actual Size

20 LIQUID GELS**
(**LIQUID-FILLED CAPSULES)

quality value

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*nonsteroidal anti-inflammatory drug

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Drug Facts (continued)

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 you have a 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

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Drug Facts (continued)

delivery.
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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, sorbitol sorbitan solution, titanium dioxide, white ink

Questions or comments?
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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-748
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
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FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
GELATIN (UNII: 2G86QN327L)
GLYCERIN (UNII: PDC6A3C0OX)
LACTIC ACID (UNII: 33X04XA5AT)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)
POVIDONE K30 (UNII: U725QWY32X)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
WATER (UNII: 059QF0KO0R)
SORBITAN (UNII: 6O92ICV9RU)
SORBITOL (UNII: 506T60A25R)
ALCOHOL (UNII: 3K9958V90M)
SHELLAC (UNII: 46N107B71O)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
LIGHT MINERAL OIL (UNII: N6K5787QVP)

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:55301-748-20	1 in 1 BOX	02/28/2018	
1		20 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	02/28/2018	

Labeler - AAFES/Your Military Exchanges (001695568)