

NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
Care One (American Sales Company)

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 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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - slurred speech
 - leg swelling
 - 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
- 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.(1-800-222-1222).

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.
- swallow whole; do not crush, chew, or dissolve

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®†

NAPROXEN SODIUM

Capsules, 220 mg

Pain Reliever; Fever Reducer (NSAID)

Strength to lasts 12 hours

CAPSULES**

**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.

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LANDOVER, MD 20785

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Product Label

Exp. Date:
Lot No.:
P.L.D-BE282A
FC004611



Drug Facts
Active ingredient (in each capsule)
Naproxen sodium 220 mg (NSAID)*
Pain reliever/fever reducer
*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
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■ 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.

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 ■ 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 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 ■ you have stomach pain that does not get better ■ chest pain ■ slurred speech ■ leg swelling ■ 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 ■ 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.

Drug Facts (continued)
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).
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. ■ swallow whole; do not crush, chew, or dissolve
Inactive ingredients FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, polydioxane, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide, white ink
Questions or comments?
Call 1-877-765-3955 Monday-Friday 9AM-5PM EST

NDC 41520-748-20

Compare to the Active Ingredient in Aleve[®]

NAPROXEN SODIUM

Capsules 220 mg *Actual Size*

Pain Reliever/
Fever Reducer (NSAID)

Strength to Last 12 Hours

20 CAPSULES**
**Liquid-Filled Capsules



CAREONE Naproxen Sodium 220 mg

*This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve[®].

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TAMPER EVIDENCE 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:41520-748
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: 3WJQ0SDW1A)	
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:41520-748-80	1 in 1 BOX	04/01/2018	
1		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41520-748-20	1 in 1 BOX	04/01/2018	
2		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	04/01/2018	

Revised: 10/2019

Care One (American Sales Company)