

CARE ONE NAPROXEN SODIUM- naproxen sodium tablet, film coated
American Sales Company

American Sales Company Naproxen Sodium Drug Facts

Active ingredient (in each caplet)

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

- 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
 - 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
- 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 (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

Adults and children 12 years and older	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • ask a doctor

Other information

- **each caplet contains:** sodium 22 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

CAREone®

Compare to the active ingredient in Aleve® Caplets

NAPROXEN SODIUM

Tablets 220mg

Pain Reliever/Fever Reducer (NSAID)

Actual Size

Strength to last 12 hours

Easy Open Arthritis Cap

PACKAGE NOT CHILD RESISTANT

200 CAPLETS**

**Capsule-Shaped Tablets

CAREone®

NDC 41520-349-82
Compare to the
active ingredient
in Aleve® Caplets*

NAPROXEN SODIUM

Tablets 220mg

Pain Reliever/
Fever Reducer (NSAID)
Strength to last 12 hours
Easy Open Arthritis Cap

Actual Size



200
CAPLETS**

**Capsule-Shaped Tablets

PACKAGE NOT
CHILD RESISTANT

GLUE AREA

GLUE AREA

This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Aleve® Caplets. DISTRIBUTED BY: ADUSA, DIST. RIBURTON, LLC SALES BUREAU, NC 28147 For product questions or concerns, contact us at 1-833-992-5872. Quality guaranteed or your money back. Gluten Free

Questions or comments?
1-800-719-9260

Inactive ingredients: F&C Blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, v.c., titanium dioxide

Other information ■ each caplet contains sodium 22 mg ■ store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Drug Facts (continued)

DO NOT USE IF PRINTED FOIL UNDER CAP
IS BROKEN OR MISSING

Drug Facts

Active ingredient **Purposes**

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Naproxen sodium 220 mg Pain reliever/
(naproxen 200 mg) (NSAID)*, fever reducer
*nonsteroidal anti-inflammatory drug

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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

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When using
this product
■ take with food



EXP LOT

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GLUE AREA

Drug Facts (continued)

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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

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



CARE ONE NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-349
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. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	L368
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-349-82	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA074661	06/13/2016	

Labeler - American Sales Company (809183973)

Revised: 3/2025

American Sales Company