

**CAREALL NAPROXEN- naproxen sodium tablet**  
**New World Imports, Inc.**

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**Active ingredients (in each caplet)**

Active ingredient (in each caplet)

Naproxen sodium 220mg

(Naproxen 200mg) (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever / fever reducer

**Uses**

Temporarily relieves minor aches and pains due to: minor pain of arthritis, backache, headache, muscular aches, menstrual cramps, toothache, 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 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 everyday 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

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If you have ever had an allergic reaction to any other pain reliever/fever reducer.

Right before or after heart surgery

### **When using this product**

#### **When using this product:**

Take with food or milk if stomach upset occurs.

### **Ask a Doctor**

#### **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 drugs

### **Stop use and ask a doctor**

#### **Stop use and ask a doctor if:**

You experience any of the following signs of stomach bleeding: you 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, or 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**

**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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

## Directions

### 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 - 12 hour period
- Do not exceed 3 caplets in a 24 hour period

### Children under 12 years:ask a doctor

## Inactive ingredients

croscarmellose sodium, FD&C blue number 2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

**Drug Facts (continued)**

**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
- 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).

**Inactive ingredients** croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

**Questions or comments?** 1-844-705-4384

NDC # 51824-072-01

Compare to the active ingredient of Aleve®

**CARE ALL**

**Naproxen**  
Sodium Tablets, 220 mg

All Day Pain Relief

Pain Relief/  
Fever Reducer (NSAID)

8-12 Hour Relief

100 CAPLETS\*\*

DO NOT USE IF WRAPPED SEAL UNDER CAP IS BROKEN OR MISSING

**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
Naproxen sodium 220 mg Pain relief/  
(naproxen 200 mg) (NSAID) Fever reducer  
nonsteroidal anti-inflammatory drug

**Uses**

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

**Warnings**

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

- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- asthma (wheezing)
- skin redness/itching
- blistering

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

Distributed by: MW, Inc.  
160 Athens Way, Nashville, TN 37228

PEEL BACK HERE FOR MORE DRUG FACTS

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This product is not manufactured or distributed by Aleve®. U.S. distributor of Aleve®.

**Drug Facts (continued)**

- 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, including naproxen, may 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 pregnant or breastfeeding
- you are taking any other drugs for pain relief 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
- 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 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).

**STOP PEELING**

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# CAREALL NAPROXEN

naproxen sodium tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51824-072
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>NAPROXEN SODIUM</b> (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	17
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-072-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/16/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	01/16/2019	

**Labeler** - New World Imports, Inc. (075372276)

