# PAIN RELIEVER- naproxen sodium tablet Productos Zapotol Corp.

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## **Drug Facts**

Active ingredient (in each caplet)
Naproxen sodium 220 mg
(naproxen 200 mg) (NSAID)\*
\*nonsteroidal anti-inflammatory drug

## **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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:** NSAID, 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 problems or serious side effects from taking pain relievers or fever reducers
- you have asthma
- you are taking a diuretic

### 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
  - trouble breathing
  - leg swelling
  - 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 pill 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
- 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

#### Other information

- each caplet contains: sodium 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

## Inactive ingredients

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

## Questions or comments?

Call **1-888-927-6865** 

## **Principal Display Panel**

#### **Artridol**

Naproxen Sodium 220 mg

Pain Reliever / Fever Reducer (NSAID)

CAPLETS\*\* (\*\*Capsule-Shaped Tablets)

#### **Artritis**

- Artritis
- Muscular Aches
- Joint Pain

## 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 / Distribuido por

**Productos Zapotol Corp.** 

38850 20th St E, Palmdale, CA 93550 888-927-6865

**Product Label** 

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rtridol

Naproxen Sodium 220 mg



🖋 Arthritis 🚀 Muscular Aches 🚀 Jaint Pain



rtridol

Noprozen Sodium 220 mg Pain reliever/Fever reducer (NSAID) 24 CAPLETS" ("Capsule-shaped Inbleh)







**ZAPOTOL ARTRIDOL Naproxen Sodium 220 mg** 

#### **PAIN RELIEVER**

naproxen sodium tablet

Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59428-068

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength

NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ) NAPROXEN SODIUM 220 mg

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

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	12mm	
Flavor		Imprint Code	17	
Contains				

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59428- 068-24	1 in 1 BOX	05/31/2017	05/31/2025	
1		24 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	ANDA079096	05/31/2017	05/31/2025	

## Labeler - Productos Zapotol Corp. (186063850)

Revised: 4/2023 Productos Zapotol Corp.