

**NAPROXEN SODIUM- naproxen sodium tablet, film coated, extended release
SPIRIT PHARMACEUTICALS,LLC**

NAPROXEN SODIUM TABLETS, USP 220 mg

Drug Facts

Active ingredients (in each tablet)	Purpose
Naproxen Sodium 220 mg	Pain reliever
(Naproxen Sodium 200mg) (NSAID) *	Fever reducer

* Nonsteroidal anti-inflammatory drug

Uses

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

Warnings

Allergy alert

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

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains a non steroidal anti-inflammatory drug(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

NSAID's except aspirin increases 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 surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as a heartburn
- you have a high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have problems or serious side effects taking pain relievers or fever reducers
- you have asthma

Ask a doctor or pharmacist before use if you are

- under a doctor 's care for any serious conditions
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

you experience any of following sign of stomach bleeding:

feel faint

vomit blood

have bloody or black stools

have stomach pain that does not get better

pain gets worse or lasts more than 10 days

fever gets worse or lasts more than 3 days

you have difficulty swallowing

it feel 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 profession 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 complication during the delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a position control center right away (1-800-222-1222)

Direction

***Do not take more than as 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 table every 8 to 12 hours while symptoms last

- for the first dose you may have take 2 tablets within the first hour

- do not exceed 2 tablets in any 8 to 12 hour period

- do not exceed 3 tablets in any 24 hour period

*Children under 12 years

- ask a doctor

Other information

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

Inactive ingredients

Colloidal silicon dioxide*, croscarmellose sodium*, FD&C Blue#2 lake, hypromellose, magnesium stearate*, maize starch*, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate*, stearic acid*, titanium dioxide.

*contains one or more of these ingredients

Distributed By: Greenbrier International, Inc. Chesapeake, VA 23320

PRINCIPAL DISPLAY PANEL - 220 mg Bottle Carton

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SEE NEW WARNINGS INFORMATION

Compare to the active ingredient in **Aleve**®*

**ALL DAY
PAIN RELIEF**

NAPROXEN SODIUM TABLETS, USP 220 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

- STRENGTH TO LAST 12 HOURS

15 TABLETS (OVAL-SHAPED)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0400
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0400-0	1 in 1 CARTON	12/22/2017	
1		15 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0400-1	1 in 1 CARTON	11/22/2017	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	11/22/2017	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Establishment			
Name	Address	ID/FEI	Business Operations
Marksans Pharma Ltd		925822975	manufacture(68210-0400)

Revised: 12/2019

SPIRIT PHARMACEUTICALS,LLC