

ALL DAY PAIN RELIEF- naproxen sodium tablet
SPIRIT PHARMACEUTICALS LLC

VALUMEDS ALL DAY PAIN RELIEF

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ fever reducer

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

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)

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 tablet every 8 to 12 hours while symptoms last• for the first dose you may 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 a 24-hour period
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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, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

1-888-333-9792

DISTRIBUTED BY

SPIRIT PHARMACEUTICALS, LLC.

RONKONKOMA, NY 11779

MADE IN INDIA

PRINCIPAL DISPLAY PANEL - 15 COUNT BOTTLE CARTON

VALUMEDS™

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)

ALL DAY PAIN RELIEF

EXP: _____

LOT: _____

0 402321605251 3



003-0015

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003-0015

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ROMKONOMA, NY 11779
MADE IN INDIA

ORG 07171

Drug Facts (continued)

- 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 advised by your health care provider. There may be some 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
- Adults and Children:
 - take 1 tablet every 8 to 12 hours
 - with meals or with or after meals
 - with the first meal
 - 2 tablets within the first hour
 - do not exceed 2 tablets in any 8 to 12 hour period
 - do not exceed 3 tablets in a 24-hour period
 - ask a doctor
- Children under 12 years:

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)

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

1-866-333-9192

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

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 are taking a diuretic
- you have problems or serious side effects from 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 condition
- 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 the following signs of stomach bleeding:
 - black or bloody stools
 - vomiting blood
- stomach pain that does not get better
- stomach pain that lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing

Drug Facts (continued)

Warnings

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

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

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

Stomach bleeding warning: This product contains a nonsteroidal 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 blood thinning (anticoagulant) or steroid drugs
- take aspirin, NSAIDs (ibuprofen, naproxen, or others), NSAIDs (aspirin, ibuprofen, naproxen, or others)

Drug Facts (continued)

Purpose

Naproxen sodium 220 mg (NSAID) pain reliever/fever reducer

Uses

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

Drug Facts (continued)

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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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

VALUMEDS 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)

Drug Facts (continued)

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Drug Facts (continued)

- take 3 or more alcoholic drinks every day while using
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Ask a doctor before use if:

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naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0030
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:68210-0030-1	1 in 1 CARTON	04/11/2018	
1		15 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	04/11/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(68210-0030)

Revised: 12/2019

SPIRIT PHARMACEUTICALS LLC