

NAPROXEN SODIUM 220MG- naproxen sodium tablet
Medline Industries

688 Naproxen 220mg

Active ingredient (in each tablet)

Naproxen sodium, USP 220 mg
(naproxen 200 mg) (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

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.

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

- 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

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
- 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

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.

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.

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 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
- children under 12 years: ask a doctor

Other information

- **each tablet 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).

Inactive ingredients

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

Package Label

Medline NDC: 53329-688-30
 *Compare to the active ingredient in Aleve®
Naproxen Sodium
 Pain reliever/Fever reducer (NSAID)
 Strength to last 12 hours
 100 Tablets **220 mg**

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

Drug Facts
Active ingredient (in each tablet) Naproxen sodium, USP 220 mg Pain reliever/fever reducer (naproxen 200 mg) (NSAID),fever reducer
 *nonsteroidal anti-inflammatory drug

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 redness ■ 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 ▼

www.medline.com Made in India for: Medline Industries, Inc., Northfield, IL 60093 RE18HND 1-800-MEDLINE
REF OTCM0012

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Aleve® Tablets.

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 PEEL HERE ▶

Lot # & Expiration Date will be printed at time of manufacture.

7 inch Copy Free Area Needed for Hinge

Drug Facts (continued)
 ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 ■ 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 heart surgery

Ask a doctor before use if ■ 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

Stop and ask a doctor if ■ you experience any of the following signs or symptoms ■ 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 feels like the pill is stuck in your throat ■ redness or swelling is present in the painful area ■ any new symptoms appear

Hear a tinnitus 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.
 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.

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 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 ■ children under 12 years: ask a doctor

Other information ■ each tablet 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).

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

NAPROXEN SODIUM 220MG

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-688
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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

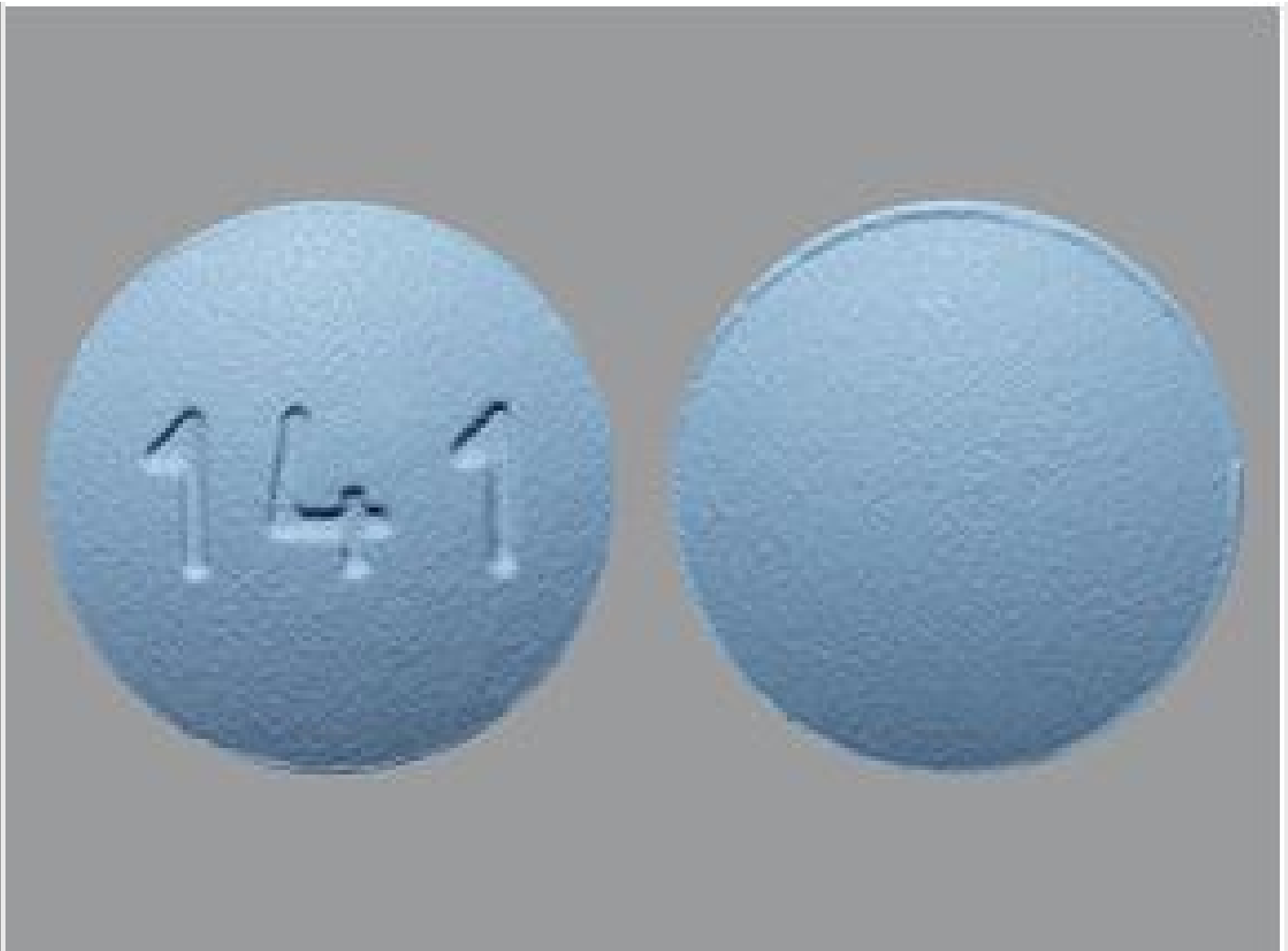
Ingredient Name	Strength
POVIDONE K90 (UNII: RDH86HJV5Z)	
WATER (UNII: 059QF0KO0R)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	score with uneven pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	141
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-688-30	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	08/01/2018	

Labeler - Medline Industries (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Medline Industries		079800021	repack(53329-688)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma		925822975	manufacture(53329-688)