

PAIN RELIEF- naproxen sodium tablet
BETTER LIVING BRANDS, LLC

608R_Albertsons_21130-608_Naproxen sodium tablets 220 mg

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- menstrual cramps
- headache
- toothache
- the 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 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

- 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, 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, 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- 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:
 1. feel faint
 2. vomit blood
 3. have bloody or black stools
 4. have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 1. chest pain
 2. trouble breathing
 3. weakness in one part or side of body
 4. slurred speech
 5. 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 at 20 weeks or later in 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

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

Questions or comments?1-877-290-4008



Quality Guaranteed

Pain Relief

NAPROXEN SODIUM TABLETS USP, 220 mg
Pain Reliever/Fever Reducer (NSAID)

Strength to last 12 hours

PACKAGE NOT CHILD-RESISTANT

ACTUAL SIZE
200 CAPLETS**
*Capsule-shaped tablets



Compare to Aleve® Caplets active ingredient! NDC 21130-608-20

DO NOT TAKE THIS PRODUCT IF THE CAPLET IS CRACKED, BROKEN OR MISSING.

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg (NSAID) (see important information about NSAIDs on the back of the bottle)

Uses

Temporarily relieves the signs and symptoms of:

- pain
- fever
- headache
- toothache
- muscle aches
- menstrual cramps
- arthritis
- sore throat
- the common cold
- flu

Warnings

• Do not take naproxen sodium if you are allergic to any of the ingredients. Symptoms of an allergic reaction may include hives, difficulty breathing, or swelling of the face, lips, tongue, or throat. Stop taking naproxen sodium immediately if you experience any of the following signs of stomach bleeding: black or bloody stools, or vomit that looks like coffee grounds. If you experience any of these symptoms, stop taking naproxen sodium immediately and seek medical help right away. Naproxen sodium 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
- 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

Drug Facts (continued under label)

This product is not intended for use in children or infants by Bayer HealthCare, LLC, owner of the registered trademark Aleve®.

DISTRIBUTED BY:

BAYER HEALTHCARE, LLC
P.O. Box 100
PLEASANTON, CA 94566-0100

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NDC 21130-608-20

Each box has the following information:

LOT: 0291305054
EXP: 12/08

Lot No.:
Exp Date:

Varnish Omit Area

OR IT'S ON US!

FREE PHONE



4 96695 0291305054

RO 23072



PLASTIC BOTTLE
RO 23072

more information

www.bayer.com

800-898-2289

www.bayer.com

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FREE PHONE

Adhesive Area

- 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, 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. **Keep out of reach of children.**
- **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
- **Questions or comments?** 1-877-290-4008

DISTRIBUTED BY: BETTER LIVING BRANDS LLC
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 41-888-723-3929
 Made in India
 608R 0223 S5394
 HD 23047
 how2recycle.info
 PLASTIC BOTTLE

LOVE IT
 OR IT'S ON US

NDC 21130-608-05



Pain Relief

NAPROXEN SODIUM TABLETS USP, 220 mg
 Pain Reliever/Fever Reducer (NSAID)

Strength to last 12 hours 50 CAPLETS**
 **Capsule-shaped tablets

DAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOR THIS USES OR THE MIDDLE OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Purposes

Active ingredient (in each caplet)
 Naproxen sodium 220 mg.....Pain reliever/fever reducer
 Naproxen 200 mg (NSAID).....Pain reliever/fever reducer
 *nonsteroidal anti-inflammatory drug

Uses

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

Drug Facts (continued under label)

Lot No:
 Exp Date:
 SEE THE BOTTOM OF THE BOTTLE

Varnish Omit Area

Print & Varnish Omit



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FOR IT'S ON US

LOVE IT

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15 E. KALAMAZOO RD. #1000

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Varnish Omit

Compare to Aleve® Caplets active ingredients!

NDC 2103-600-05



ACTUAL SIZE

50 CAPLETS**

**Caplets shaped like Aleve®

Pain Relief

NAPROXEN SODIUM TABLETS USP, 220 mg Pain Reliever/Fever Reducer (NSAID)

Strength to last 12 hours



Quality Guaranteed

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

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION



ACTUAL SIZE

Drug Facts (continued)

pressure, heart disease, liver or kidney disease, asthma, or had a stroke. Do not take if you are taking a diuretic. Do not take if 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. Do not take aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin. Do not take any other drug.

When using this product: Do not 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: heartburn, vomit, blood, or 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; big 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 or any new symptoms appear.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in 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. In 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.

Drug Facts (continued)

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 include: colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #2 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, titanium dioxide.

Questions or comments? 1-877-290-4808

Drug Facts

Active ingredient (in each caplet): Naproxen sodium 220 mg. Purpose(s): Pain reliever/fever reducer. (Naproxen 220 mg, NSAID) NSAID: nonsteroidal anti-inflammatory drug.

Use: temporarily relieves minor aches and pains due to: minor pain of arthritis; muscular aches; backache; menstrual cramps; headache; toothache; the common cold; temporarily reduce 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; 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, 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 or right before or after heart surgery.

Ask a doctor before use if: you have stomach bleeding warning applies to you; you have a history of stomach problems, such as heartburn; you have high blood pressure.



PAPER BOX PLASTIC BOTTLE

E1891

Varnish Omit

Varnish Omit



NDC 21130-608-42

Pain Relief

NAPROXEN SODIUM TABLETS USP, 220 mg
Pain Reliever/Fever Reducer
(NSAID)

Strength to last 12 hours **24 CAPLETS****
**Capsule-shaped tablets

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mgPain reliever, fever reducer
(naproxen 200 mg) (NSAID)* NSAID = nonsteroidal anti-inflammatory drug

Uses

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

Drug Facts (continued under label)

Lot No:
 PEEL HERE
 Exp Date:

Varnish Omit Area

Adhesive Area

LOVE IT
OR IT'S ON US!



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P.O. BOX 99, PLASANTON, CA 94566-0099
415-888-725-3929
Made in India
60881 0223 55934

Children under 12 years: ask a doctor

Questions or comments?
1-877-290-4008

- do not exceed 3 caplets in a 24-hour period
- do not exceed 2 caplets in any 8- to 12-hour period
- 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 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

if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

Directions

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.

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



PAIN RELIEF

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-608
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
CROSCARMELOSE SODIUM (UNII: M280L1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-608-42	1 in 1 CARTON	06/13/2023	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-608-05	1 in 1 CARTON	06/13/2023	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-608-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	06/13/2023	

Labeler - BETTER LIVING BRANDS, LLC (009137209)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(21130-608)