

**ALL DAY PAIN RELIEF- naproxen sodium tablet
ASSURED / DOLLAR TREE (Greenbrier International, Inc.)**

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 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

- 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 attach and stroke warning: NSAIDs, except aspirin, increase the risk of heart attach, 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 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
- 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
- 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 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 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 any 24-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).
- 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 and titanium dioxide

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO ACTIVE INGREDIENT OF Aleve®†

All Day Pain Relief

- Naproxen Sodium Tablets, 220 mg

Pain Reliever / Fever Reducer (NSAID)

tablets

†This product is not manufactured or distributed by Bayer Healthcare, LLC, distributor

of Aleve®.

**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

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Package Label

Lot No.:
Exp. Date:

PLD-A1166
FC006821



DISTRIBUTED BY
GREENRIEVE INTERNATIONAL, INC.
500 VOYVO PARKWAY, CHESAPEAKE, VA 23320

Drug Facts	Purposes
Active ingredient (in each tablet) Naproxen sodium, USP 220 mg (naproxen 200 mg (NSAID)*, nonsteroidal anti-inflammatory drug)	Pain reliever/fever reducer
Uses temporarily relieves minor aches and pains due to: headache toothache menstrual cramps muscular aches backache temporarily reduces fever minor pain of arthritis 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: rash asthma (wheezing) hives stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug 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: 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.	

Drug Facts (continued)
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 have problems or serious side effects from taking pain relievers or fever reducers 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 you have symptoms of heart problems or stroke: chest pain 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

Drug Facts (continued) 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 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). read all warnings and directions before use. Keep carton.
Inactive ingredients crosscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

ASSURED COMPARE TO ACTIVE INGREDIENT OF **ALEVE®†**
NDC 33992-0169-4

All Day Pain Relief

• Naproxen Sodium Tablets, 220 mg
Pain Reliever / Fever Reducer (NSAID)

60% MORE **24 tablets**
Actual Size

ASSURED All Day Pain Relief

ALL DAY PAIN RELIEF

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0169
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: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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	10mm
Flavor		Imprint Code	I3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0169-4	1 in 1 BOX	03/13/2020	
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	03/13/2020	

Labeler - ASSURED / DOLLAR TREE (Greenbrier International, Inc.) (610322518)