

NAPROXEN CAPLETS ALL DAY RELIEF FOR PAIN- naproxen sodium 220 mg tablet
Allegiant Health

Drug Facts

Active ingredient

Naproxen sodium 220mg
(naproxen 200mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

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 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 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: 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

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 immediately

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

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). Do not use if tamper evident seal under bottle cap is broken or missing.

Inactive Ingredients

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

Package/Label Principal Display Panel

Drug Facts (continued)

3 days ■ 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 (1-800-222-1222) 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 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

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Inactive ingredients: FD&C blue #2 aluminum lake, hydroxyethylcellulose, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Drug Facts (continued)
cellulose, polyethylene glycol, povidone, titanium dioxide

May contain: corn starch, croscarmellose sodium, magnesium stearate, purified water, silicon dioxide, sodium starch glycolate, stearic acid

Questions or Comments?
Call 1-888-952-0050
Monday through Friday 9AM-5PM EST

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

LBI606 R0220

Compare to Aleve® active ingredient**

ALL DAY RELIEF FOR PAIN

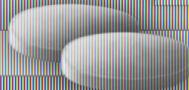
Naproxen

(NSAID)*

Naproxen Sodium

220mg

10 Caplets



See new warning information

Drug Facts

Active ingredient
(in each caplet)
Naproxen sodium 220mg.....fever reducer (naproxen 200mg) (NSAID)*

Purposes
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 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,

Drug Facts (continued)

heart failure, and stroke. These can be fatal. This 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

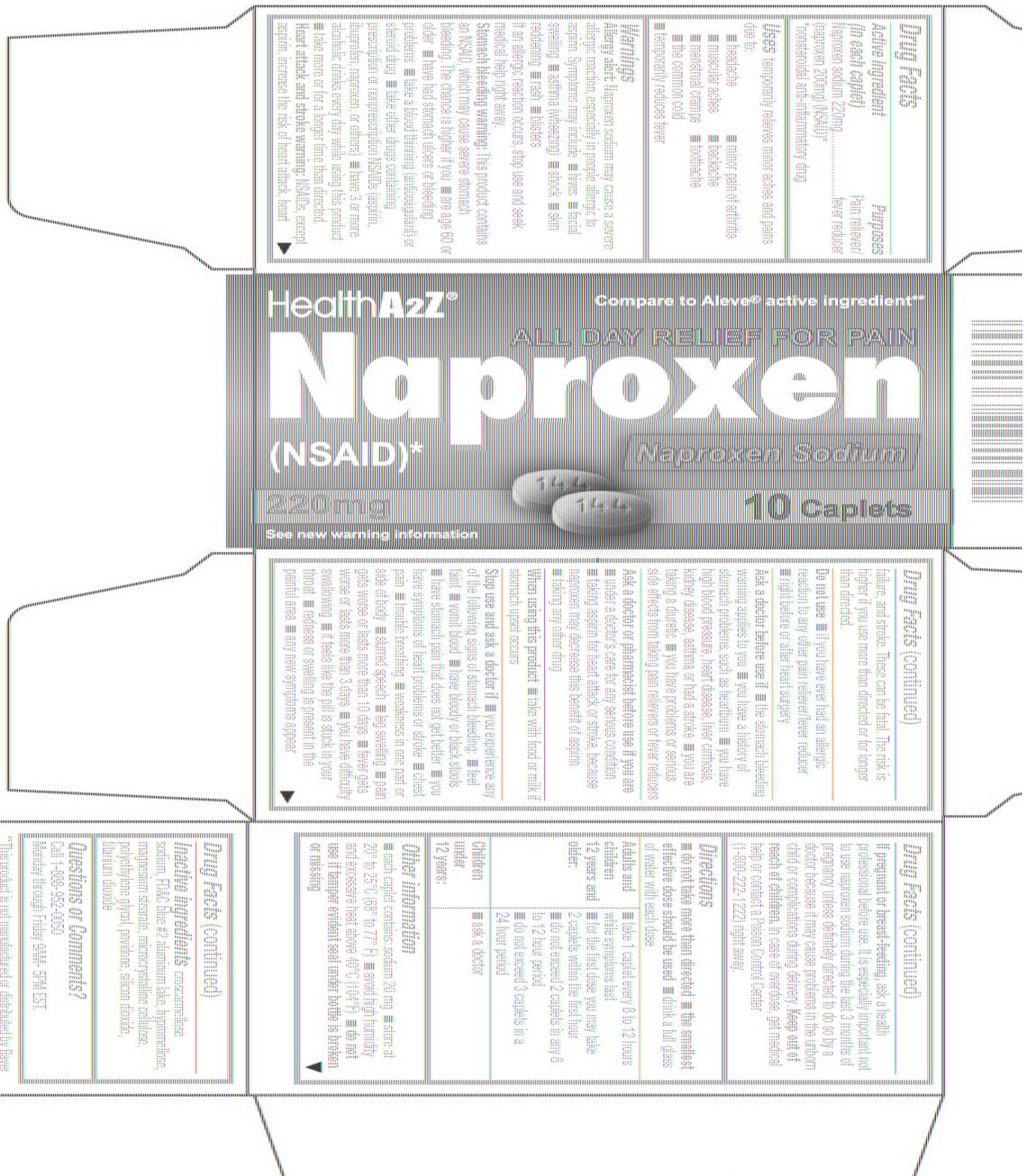
Ask a doctor before use if ■ the stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver problems, or kidney disease ■ you are taking a diuretic ■ you have problems or serious side effects from taking pain 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 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 ■ 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: ■ 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 ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than

Naproxen



Naproxen

NAPROXEN CAPLETS ALL DAY RELIEF FOR PAIN

naproxen sodium 220 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-362
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-362-07	1 in 1 CARTON	12/23/2014	
1		10 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	12/23/2014	

Labeler - Allegiant Health (079501930)

Revised: 11/2018

Allegiant Health