

NAPROXEN SODIUM- naproxen sodium tablet, coated
Kroger Company

609R Kroger 41226 609 Naproxen Sodium tablets USP,220mg 50ct

DRUG FACTS

Active ingredient (in each caplet)

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

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:
 - 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 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 a 24-hour period

Children under 12 years:

- ask a doctor

OTHER INFORMATION

Other information

- each tablet 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 no. 2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments? 1-800-632-6900

NDC 41226-609-05

Kroger

Strength To Last 12 Hours

Naproxen Sodium Tablets USP, 220 mg

Pain Reliever/
Fever Reducer
(NSAID)

50 TABLETS

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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
aspirin 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. 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 a 24-hour period

Children under 12 years: ■ ask a doctor

Other information ■ **TAMPER EVIDENT: DO NOT USE THIS
PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH
OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**
■ each tablet contains: sodium 20 mg ■ store at 20-25°C
(68-77°F) ■ avoid high humidity and excessive heat above 40°
C (104°F) ■ Questions or comments? 1-800-632-6900

MADE IN INDIA Code No: G0DRUGS515
DIST. BY THE KROGER CO., CINCINNATI, OHIO 45202
FOR MORE PRODUCT INFORMATION, SCAN UPC
USING YOUR KROGER APP OR CALL 800-632-6900
● 藥廠批發 ● BUI1426
Lot No.:
Exp. Date:

609R REV 04/21

0 41260 01304 1

80% SIZE
12-P FPO (non-FDA)
For Position Only

DISTRIBUTED BY THE KROGER CO.
MADE IN INDIA
FOR MORE PRODUCT INFORMATION, SCAN UPC
USING YOUR KROGER APP OR CALL 1-800-632-6900

Lot No.:
Exp. Date:

Drug Facts

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

Purposes

Uses ■ temporarily relieves minor aches and pains due to: ■ minor pain or arthritis ■ muscular aches ■ headache ■ menstrual cramps ■ headache ■ 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) ■ stomach pain ■ dizziness ■ 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 risks are 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, or other health problems

Drug Facts (continued)

■ fever/flu, 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: ■ heart burn ■ vomit ■ blood ■ have bloody or black stools ■ have stomach pain ■ have dark or get black stools ■ have symptoms of bleeding ■ weakness in one part or side of the body ■ slurred speech ■ 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 genital area ■ any new symptoms appear

In pregnant or breast-feeding, ask a health professional before use. It is expected that use of naproxen sodium will result in fetal or neonatal complications 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 under 12 years: ■ take 1 tablet every 8 to 12 hours while symptoms last ■ or the first dose you may take 2 tablets ■ wait the next 2 tablets in any 8- to 12-hour period ■ do not exceed 3 tablets in a 24-hour period

Drug Facts (continued)

Other information ■ each tablet 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, polyvinyl, titanium dioxide

Questions or comments 1-800-632-6900



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 INFORMATION

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COMPARE TO the active ingredient of ALEVE® TABLETS ***See top panel

NDC 41226-609-05

Kroger

Strength To Last 12 Hours

Naproxen Sodium Tablets USP, 220 mg

Pain Reliever/Fever Reducer (NSAID)

actual size

OUR PHARMACIST RECOMMENDED

50 TABLETS

NAPROXEN SODIUM naproxen sodium tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-609
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	141
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-609-05	1 in 1 CARTON	06/12/2021	
1		50 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	06/12/2021	

Labeler - Kroger Company (006999528)**Registrant** - TIME CAP LABORATORIES, INC. (037052099)**Establishment**

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-609)

