

NAPROXEN SODIUM- naproxen sodium tablet
Geri-Care Pharmaceutical Corp

gc 951

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 pain due to:

- backache
- muscular aches
- minor pain of arthritis
- 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.

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 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

- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have a 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 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:	<ul style="list-style-type: none">• take 1 tablet every 8 to 12 hours while symptoms last• for 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:	<ul style="list-style-type: none">• ask a doctor

Storage

- Store at 20-25 °C (68-77 °F). Avoid high humidity and excessive heat above 40 °C (104 °F)

Other information

- **each tablet contains:** sodium 20 mg
- If side effects occur, you may report side effects to FDA at 1-800-FDA-1088

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?

Call 1-800-540-3765

Principal Display Panel

HEALTH STAR
NDC 57896-951-01
The Same Good For Pain and Heart.

NAPROXEN SODIUM

Pain Reliever / Fever Reducer
(NSAID) nonsteroidal anti-inflammatory drug

Strength to last 12 HOURS

Compare to the active ingredient in ALEVE®*

100 Tablets
220 mg Each

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (NSAID)*
(Naprox 200 mg) (NSAID)*
nonsteroidal anti-inflammatory drug

Pain Reliever/ Fever Reducer

Uses ■ Temporarily relieves minor aches and pains due to:
 headache menstrual cramps
 backache minor pain of arthritis muscular aches
 the common cold toothache

■ Temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
 - asthma (wheezing)
 - rash
 - shock
 - skin redness
 - facial swelling
- 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 ■ 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 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

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

DIST. BY: GER-CARE PHARMACEUTICALS CORP.
 1650 63rd Street, Brooklyn, NY 11204

Made in India



REV 0815

PEEL HERE FOR MORE DRUG FACTS

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
 ever 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.

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 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F) ■ If side effects occur, you may report side effects to FDA at 1-800-FDA-1088

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

Questions or comments?
 Call 1-800-540-3765

STOP PEELING

NAPROXEN SODIUM			
naproxen sodium tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-951
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)			
CROSCARMELLOSE 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	12mm
Flavor		Imprint Code	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-951-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	
2	NDC:57896-951-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	
3	NDC:57896-951-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	05/01/2012	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceutical Corp		611196254	repack(57896-951)

Revised: 12/2018

Geri-Care Pharmaceutical Corp