

**NAPROXEN- naproxen sodium tablet**  
**Safetec of America, Inc.**

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***Drug Facts***

**Active ingredient (in each tablet)**

Naproxen sodium 220 mg (NSAID)\*\*

**Purposes**

Pain reliever/fever reducer (naproxen 200 mg) \*\* 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
- 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 had 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
  - 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.

**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"><li>▪ take 1 tablet every 8 to 12 hours while symptoms last</li><li>▪ for the first dose you may take 2 tablets within the first hour</li><li>▪ do not exceed 2 tablets in any 8- to 12-hour period</li><li>▪ do not exceed 3 tablets in a 24-hour period</li></ul>
Children under 12 years	<ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>

### 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

FD&C blue#2 aluminum lake, hypromellose, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

### Questions or comments?

Call toll free: **1-800-456-7077**

### Principal Display Panel – Pouch Label

**Safetec**  
of America, Inc.

**DO NOT USE IF POUCH IS TORN OR DAMAGED**

*Manufactured for Safetec of America, Inc.*

*Buffalo NY 14215*

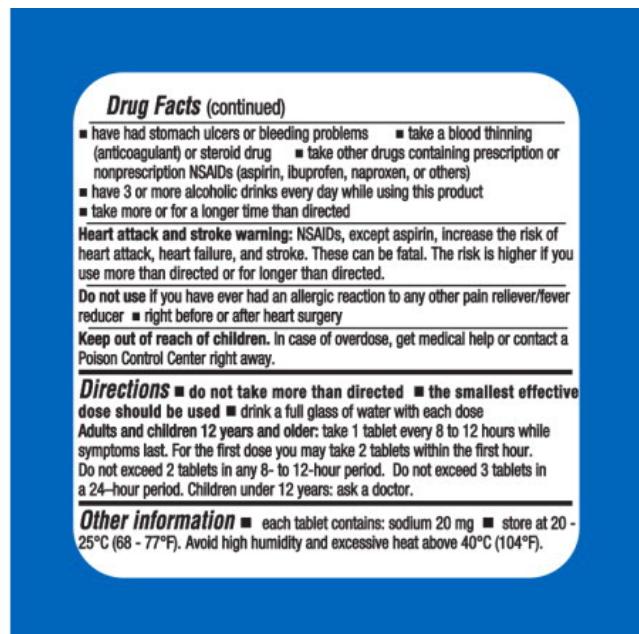
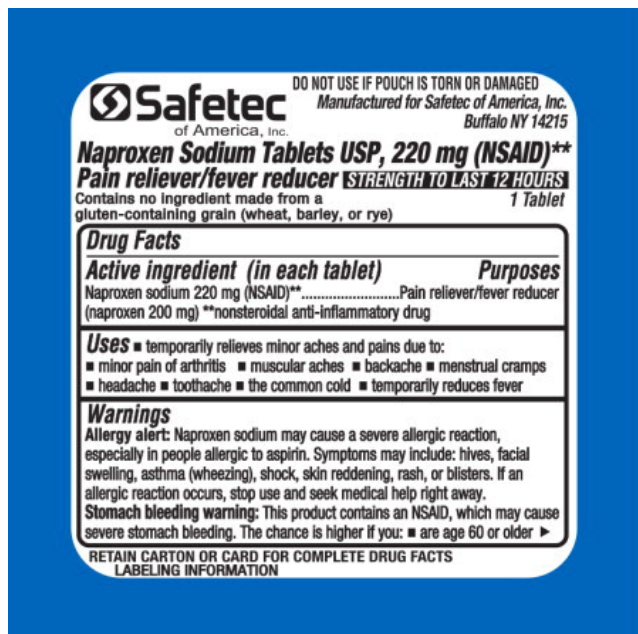
*Naproxen Sodium Tablets USP, 220 mg (NSAID)\*\**

*Pain reliever/fever reducer*

**STRENGTH TO LAST 12 HOURS**

**Contains no Ingredient made from a  
gluten-containing grain (wheat, barley, or rye)**

**1 Tablet**



## Principal Display Panel – 50-Pouch Carton Label

**Safetec<sup>®</sup>**  
**of America, Inc.**

**Compare to the active ingredient**  
**in Aleve<sup>®</sup> Tablets\***

NDC 61010-4410-1

**STRENGTH TO LAST 12 HOURS**

**Naproxen Sodium**

**Tablets USP, 220 mg (NSAID)\*\***

**Pain Reliever/Fever Reducer**

**PUSH TO OPEN**

**Dispense through**  
**opening**

**Contains no ingredient made from a gluten-containing**  
**grain (wheat, barley, or rye)**

- Relieves minor aches and pains
- Fever reducer
- Lasts up to 12 hours

**TAMPER EVIDENT UNIT DOSE POUCHES**

**DO NOT USE IF POUCH IS TORN OR DAMAGED**

**50 Pouches**

**1 Tablet per Pouch**

FOLD



Compare to the active ingredient in Aleve® Tablets\*

NDC 61010-4410-1

STRENGTH TO LAST 12 HOURS

# Naproxen Sodium

Tablets USP, 220 mg (NSAID)\*\*

PUSH TO OPEN  
Dispense through  
opening

Pain Reliever/Fever Reducer

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

- Relieves minor aches and pains
- Fever reducer
- Lasts up to 12 hours

TAMPER EVIDENT UNIT DOSE POUCHES  
DO NOT USE IF POUCH IS TORN OR DAMAGED

50 Pouches 1 Tablet per Pouch

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

## Drug Facts

### Active ingredient (in each tablet)

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

### Purposes

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### Uses

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**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.

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**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 had 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

50 Pouches 1 Tablet per Pouch

TAMPER EVIDENT UNIT DOSE POUCHES  
DO NOT USE IF POUCH IS TORN OR DAMAGED

- Relieves minor aches and pains
- Fever reducer
- Lasts up to 12 hours

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Tablets USP, 220 mg (NSAID)\*\* - Pain Reliever/Fever Reducer

# Naproxen Sodium

STRENGTH TO LAST 12 HOURS



## Principal Display Panel – 100-Pouch Carton Label

**Safetec®  
of America, Inc.**

**Compare to the active ingredient  
in Aleve® Tablets\***

NDC 61010-4410-2

***STRENGTH TO LAST 12 HOURS***

***Naproxen Sodium***

***Tablets USP, 220 mg (NSAID)\*\****

***Pain Reliever/Fever Reducer***

***Contains no ingredient made from a gluten-containing  
grain (wheat, barley, or rye)***

- **Relieves minor aches and pains**
- **Fever reducer**
- **Lasts up to 12 hours**

***PUSH TO OPEN***

***Dispense  
through  
opening***

**TAMPER EVIDENT UNIT DOSE POUCHES**

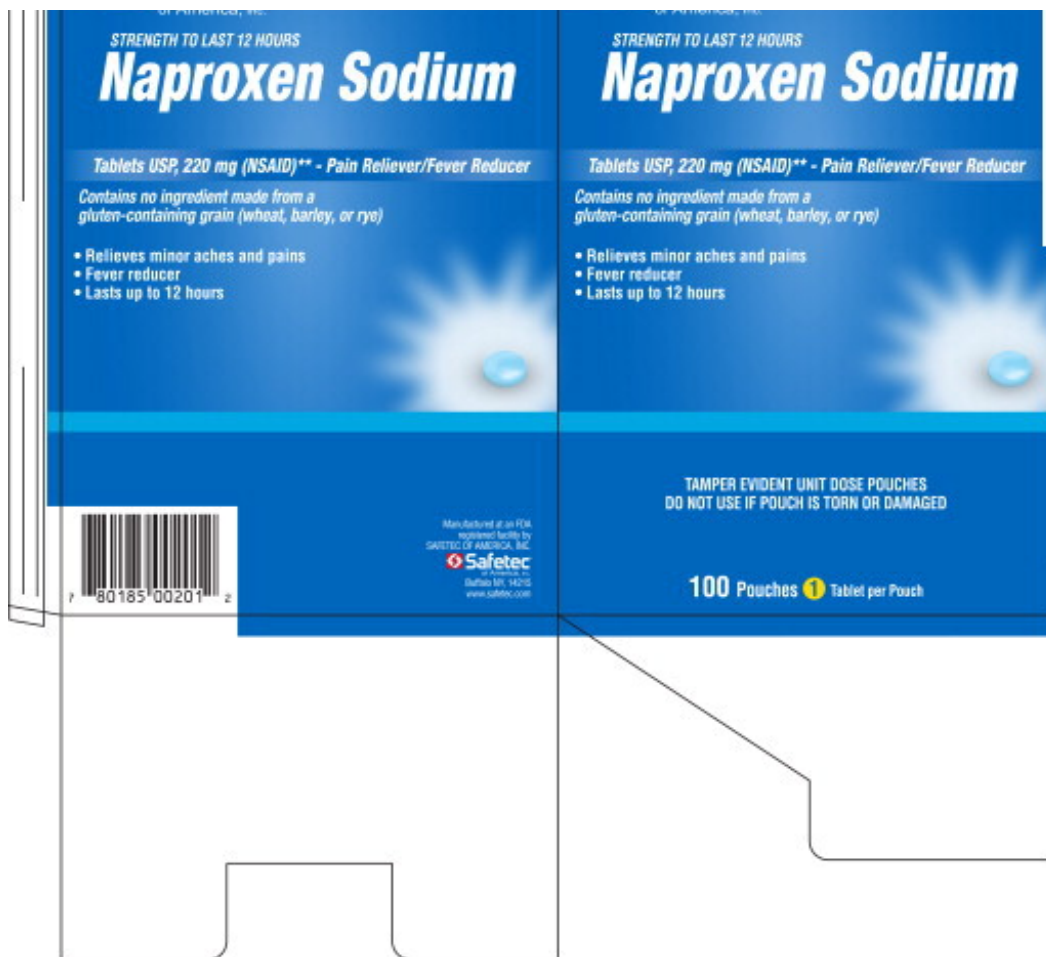
**DO NOT USE IF POUCH IS TORN OR DAMAGED**

**100 Pouches**

**1 Tablet per Pouch**







## NAPROXEN

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 10 10-4410
<b>Route of Administration</b>	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)	
Starch, Corn (UNII: O8232NY3SJ)	
Sodium Starch Glycolate Type A Potato (UNII: 5856J3G2A2)	
Povidone K30 (UNII: U725QWY32X)	
Water (UNII: 059QF0K00R)	
Stearic acid (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)

### Product Characteristics

Color	blue (blue)	Score	no score
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	220
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-4410-0	1 in 1 POUCH; Type 0: Not a Combination Product	01/20/2020	
2	NDC:61010-4410-1	50 in 1 CARTON	01/20/2020	
2	NDC:61010-4410-0	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:61010-4410-2	100 in 1 CARTON	01/20/2020	
3	NDC:61010-4410-0	1 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	01/20/2020	

**Labeler** - Safetec of America, Inc. (874965262)

Revised: 1/2020

Safetec of America, Inc.