NAPROXEN SODIUM- naproxen sodium tablet
TARGET CORPORATION

Naproxen Sodium 220 mg Tablets

Pain Reliever / Fever Reducer (NSAID)**
• Strength to last 12 hours
• Contains no ingredient made from a glutencontaining grain (wheat, barley, or rye)

Active ingredient

(in each caplet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)**

**nonsteroidal anti-inflammatory drug

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

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,

a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in 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 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- to12-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).

Inactive Ingredients

FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium
starch glycolate, stearic acid, titanium dioxide

Questions or Comments?

call **1-877-770-3183** Mon – Fri 9:00 AM to 4:00 PM EST

Principal Display Panel

COATING
FREE AREA

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Drug Facts (continued)

- 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
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  - 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
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  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
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COATING
FREE AREA

Drug Facts (continued)

- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

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Questions or comments?
call 1-877-770-0183 Mon – Fri 8:00 AM EST to 5:00 PM PST

Satisfaction guaranteed – Love it or your money back.

NDC 11673-764-05

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up&up

50 CAPLETS***
***CAPSULE-SHAPED TABLETS

Compare to active ingredient in Aleve® Caplets*

Naproxen Sodium

220 mg Tablets
Pain Reliever / Fever Reducer (NSAID)**

- Strength to last 12 hours
- Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

12 Hours

Actual Size
50 Caplets

094 01 4119 R00 C-002262-01-034-0000

8 13874 02075 9

Lot
Exp.

COATING
FREE AREA

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)**	Pain reliever/fever reducer

**nonsteroidal anti-inflammatory drug

Uses
- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - backache
  - headache
  - the common cold
  - muscular aches
  - menstrual cramps
  - 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
- facial swelling
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- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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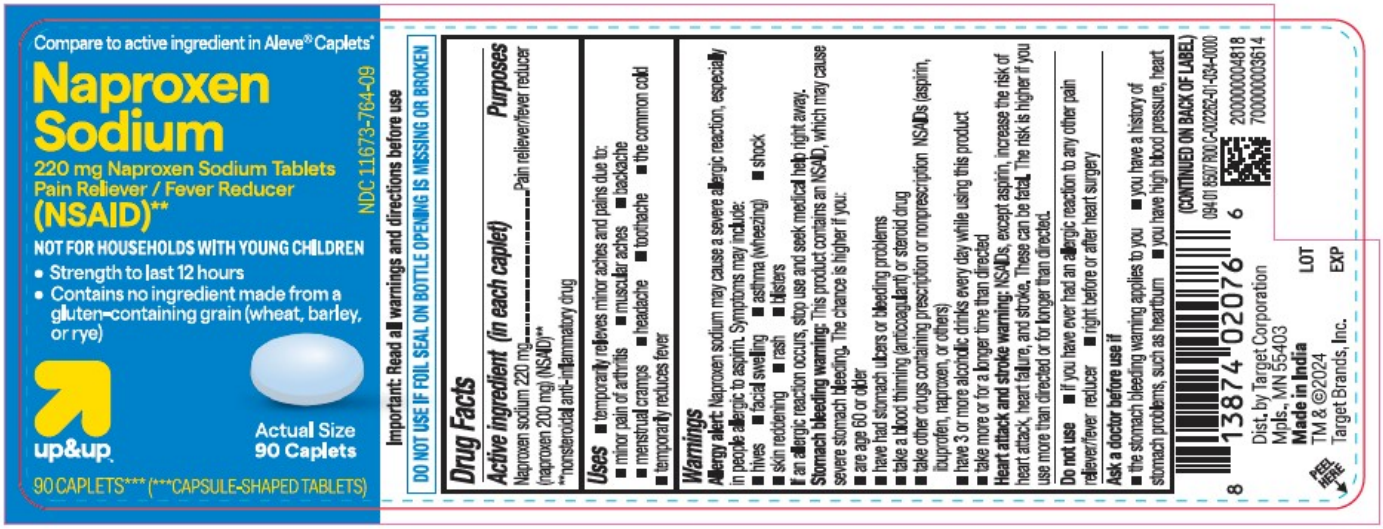
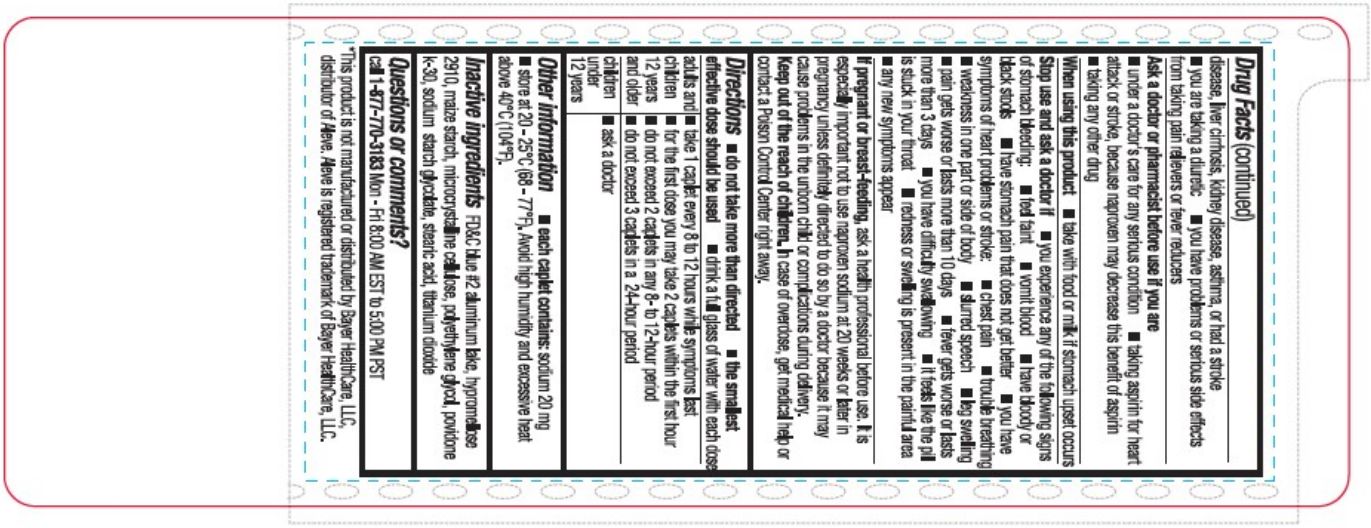


Inside (adhesive side)



NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-764
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**

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (blue (Light Blue))	**Score**	no score
Shape	OVAL (Caplet -Shaped)	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-764-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:11673-764-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	03/01/2024	

Labeler - TARGET CORPORATION (006961700)

Revised: 11/2024 TARGET CORPORATION