

NAPROXEN SODIUM- naproxen sodium tablet, coated
AAA Pharmaceutical, Inc.

RES - 1145 - 2019-0911

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID ¹)

¹ nonsteroidal anti-inflammatory drug

Purpose

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

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 asthma
- 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
- long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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
- you develop heartburn
- 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

| | |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| adults and children 12 years and older | <ul style="list-style-type: none"> • 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 • do not exceed 3 caplets in a 24-hour period |
| children under 12 years | <ul style="list-style-type: none"> • 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).
- retain carton for complete product information

Inactive ingredients

croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

RESTORE u

NDC 57344-145-01

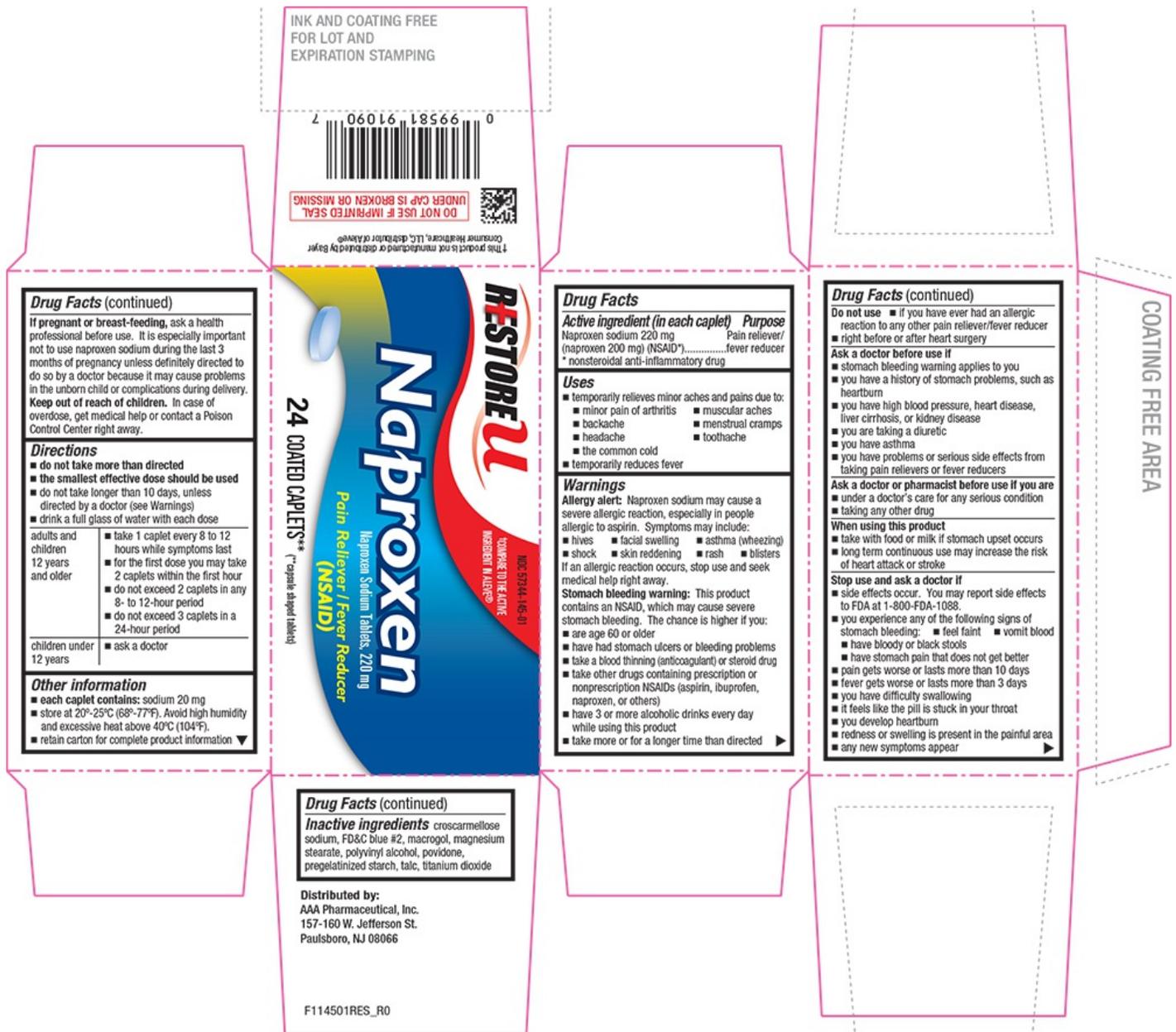
†COMPARE TO THE ACTIVE INGREDIENT IN ALEVE®

Naproxen

Naproxen Sodium Tablets, 220 mg

Pain Reliever / Fever Reducer
(NSAID)

24 COATED CAPLETS** (**capsule shaped tablets)



NAPROXEN SODIUM

naproxen sodium tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:57344-145 |
| 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 |
|-----------------|----------|
|-----------------|----------|

| | |
|------------------------------------------------------------|--|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-----------------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL (Biconvex) | Size | 12mm |
| Flavor | | Imprint Code | I7 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:57344-145-01 | 1 in 1 CARTON | 04/01/2012 | |
| 1 | | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:57344-145-02 | 1 in 1 CARTON | 04/01/2012 | |
| 2 | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANDA | ANDA079096 | 04/01/2012 | |

Labeler - AAA Pharmaceutical, Inc. (181192162)