ALL DAY PAIN RELIEF NAPROXEN SODIUM- naproxen sodium tablet
Camber Consumer Care

All Day Pain Relief Naproxen Sodium Tablets, USP 220 mg

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 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
- blisters
- skin reddening
- rash

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

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
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

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
- **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).
- 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?

1-888-588-1418

Principal Display Panel

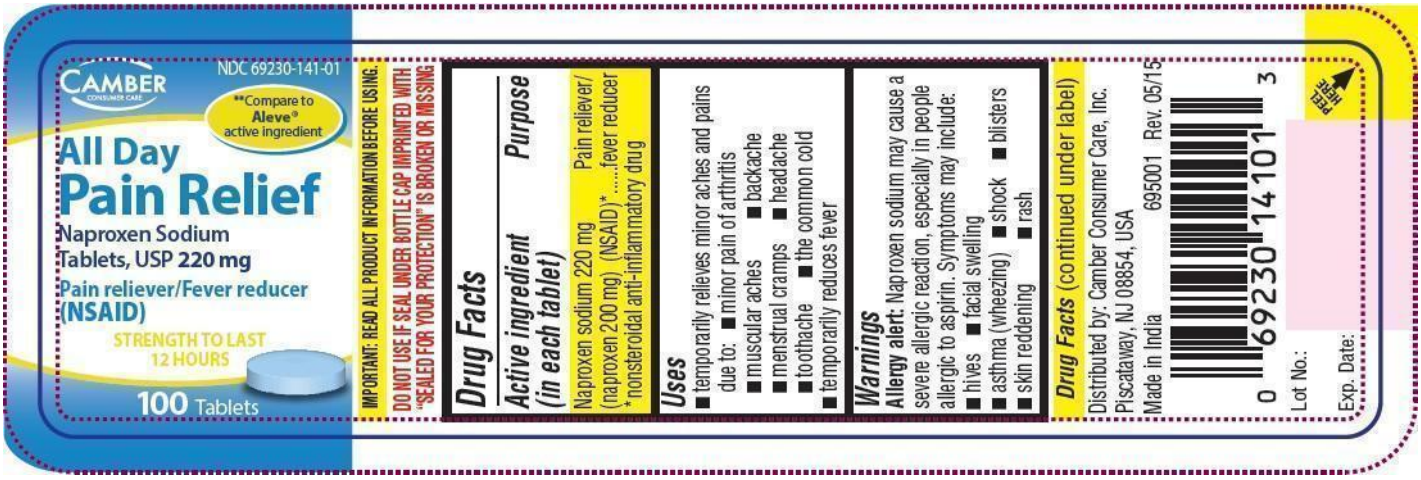
**Compare to Aleve® active ingredient

Naproxen Sodium Tablets, USP 220 mg

Pain Reliever / Fever Reducer (NSAID)

Strength to Last 12 Hours

100 TABLETS



Drug Facts (continued)

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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 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

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

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■ any new symptoms appear
■ you have difficulty swallowing

Drug Facts (continued under label)

Drug Facts (continued)

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Inactive ingredients

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Questions or comments?

1-888-588-1418

**This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Aleve®.

ALL DAY PAIN RELIEF NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69230-141
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**
COLLOIDAL 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 GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:69230-141-01	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-141-05	500 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69230-141-11	1000 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	05/26/2015	

Labeler - Camber Consumer Care (079539968)

Registrant - Camber Consumer Care (079539968)

Revised: 5/2015 Camber Consumer Care