NAPROXEN SODIUM CAPLETS- naproxen sodium tablet
Breeden Brothers, LLC

Naproxen Sodium Caplets

Drug Facts

Active ingredient (in each caplet)

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

Purpose

Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug

Uses

_ temporarily relieves minor aches and pains due to:

_ toothache _ muscular aches _ the common cold

_ headache _ menstrual cramps

_ backache _ minor pain of arthritis

_ temporarily reduces fever

Drug Facts (continued)

Warnings

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

_ asthma (wheezing) _ skin reddening _ shock

_ blisters _ rash _ facial swelling _ hives

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 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 a blood thinning (anticoagulant) or steroid drug

_ take more or for a longer time than directed

Drug Facts (continued)

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 have asthma

_ you have problems or serious side effects from taking pain relievers or fever reducers

_ you are taking a diuretic

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

Drug Facts (continued)

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

_ 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 (1-800-222-1222) right away.

Drug Facts (continued)

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- to 12-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

_ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

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

_ use by expiration date on package

Drug Facts (continued)

Inactive ingredients

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

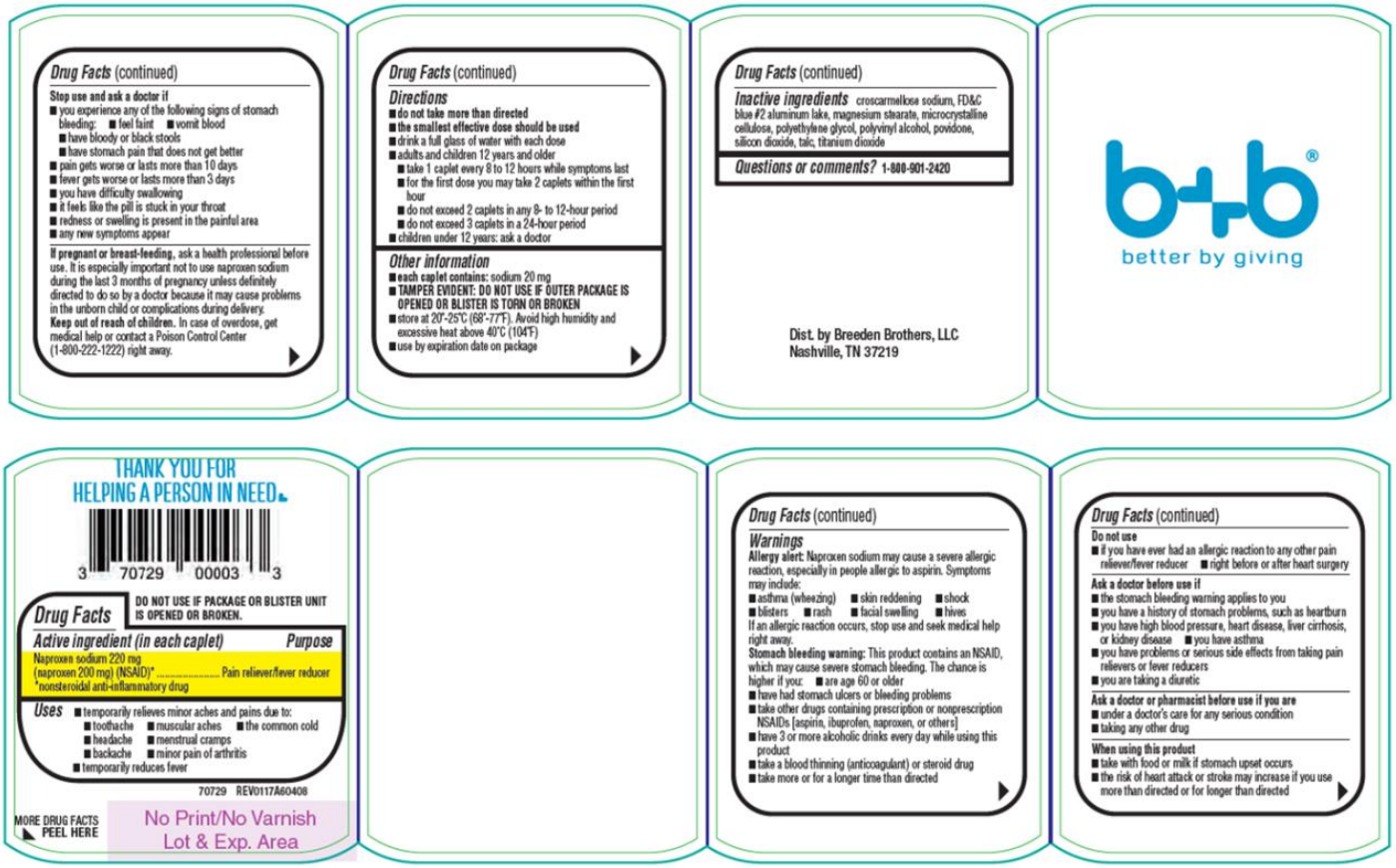
Questions or comments?

1-800-901-2420

Dist. by Breeden Brothers, LLC
Nashville, TN 37219

PRINCIPAL DISPLAY PANEL

b+b
better by giving



NAPROXEN SODIUM CAPLETS

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70729-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	220 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	44;604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70729-003-24	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
2	NDC:70729-003-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	02/01/2017	

Labeler - Breeden Brothers, LLC (080131046)

Revised: 2/2017 Breeden Brothers, LLC