

BELMORA FLANAX- naproxen sodium tablet, film coated
Unifirst First Aid Corporation

Belmora Flanax Private Label Distributor

Drug Facts

Active ingredient

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

Purpose

Pain reliever/fever reducer

Uses

Temporary 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
- 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 stomach ulcers or bleeding problems
- take a blood thinner (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:

NSAID, 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 ever have 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, 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 for more than 10 days

■ fever gets worse or lasts for 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 accidental 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: (12 years of age 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 68-77°F (20-25°C)
- avoid high humidity and excessive heat above 104°F (40°C)
- tamper evident sealed packets
- do not use any open or torn packets

Inactive ingredients

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

Questions or comments?

1-888-779-2877

M-F 9AM-5PM EST

Belmora LLC, 2231 Crystal Dr. Suite 1000, Arlington, VA 22202

**Source NDC 47682-237
PLD Belmora Flanax Label**

Flanax®

Pain Reliever/Fever Reducer

Longer Lasting Pain Relief

For Temporary Relief Of Minor Aches & Pains

20 Dual Packets

1 Tablet Per Packet

40 Tablets

220MG Tablets Naproxen Sodium USP (NSAID)

Drug Facts

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(in each tablet).....Pain reliever/fever reducer
Naproxen Sodium USP 220 mg
(naproxen 200 mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

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 - muscular aches
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 - menstrual cramps
 - headache
 - toothache
 - the common cold
- Temporarily reduces fever

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Drug Facts (continued)

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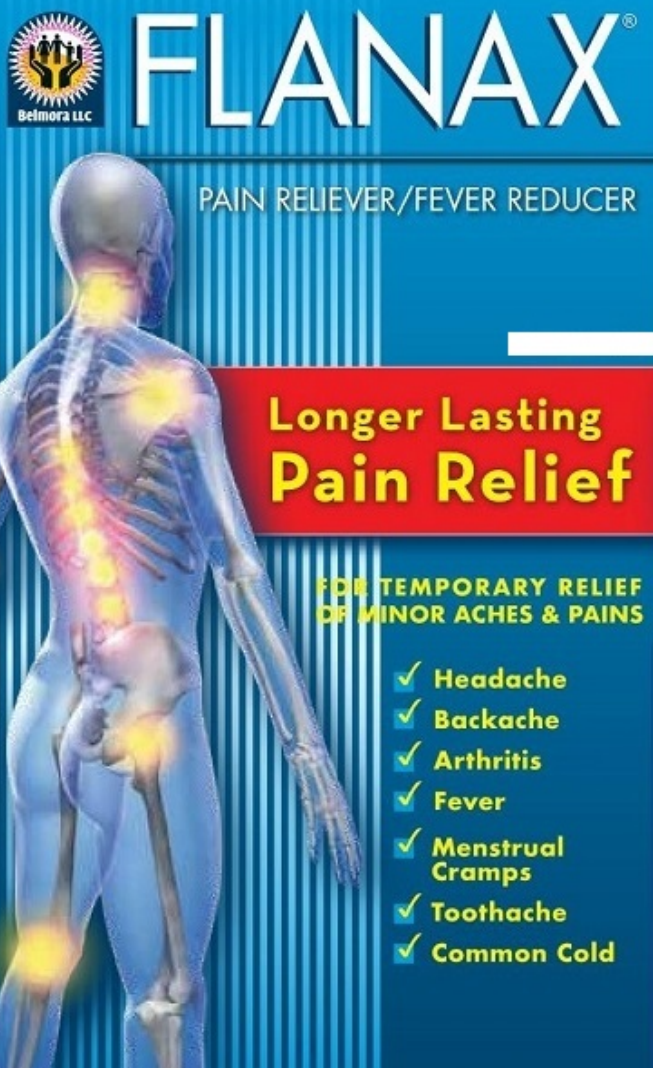
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Belmora LLC, 2011 Crystal Dr. Suite 400, Arlington, VA 22202



FLANAX[®]

PAIN RELIEVER/FEVER REDUCER

Longer Lasting Pain Relief

FOR TEMPORARY RELIEF OF MINOR ACHES & PAINS

- ✓ Headache
- ✓ Backache
- ✓ Arthritis
- ✓ Fever
- ✓ Menstrual Cramps
- ✓ Toothache
- ✓ Common Cold

20 DUAL PACKETS

1 TABLET PER PACKET | 40 TABLETS

220MG TABLETS NAPROXEN SODIUM USP (NSAID)

BELMORA FLANAX

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-037
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:5Y7Y6R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients

Ingredient Name	Strength

POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	I;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-037-50	50 in 1 BOX	12/30/2008	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	12/30/2008	

Labeler - Unifirst First Aid Corporation (832947092)

Registrant - Prestige Packaging (170837962)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		080667761	pack(47682-037)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		831227801	manufacture(47682-037)