FLANAX PAIN RELIEVER/FEVER REDUCER- naproxen sodium tablet, coated
Belmora LLC

FLANAX PAIN RELIEVER / FEVER REDUCER

Drug Facts

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 pain due to: ■ headache ■ muscular aches ■ toothache ■ the common cold ■ backache ■ menstrual cramps ■ minor pain of arthritis

■ temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ shock ■ facial swelling ■ asthma (wheezing) ■ hives ■ skin reddening ■ blisters ■ 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

■ have had stomach ulcers or bleeding problems

■ take blood thinning (anticoagulant) or steroid drug

■ are age 60 or older

■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

■ take more or for a longer time than directed

■ have 3 or more alcoholic drinks every day while using this product.

Heart attack and stroke warning: NSAIDs, except aspirin, increases 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 are taking a diuretic

■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

■ you have a 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: ■ leg swelling ■ chest pain ■ slurred speech ■ trouble breathing ■ weakness in one part or side of body

■ 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 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 tablet every 8 to12 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)

■ see end flap for expiration date and lot number

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?

Call 1-888-779-2877 M-F 9AM-5PM EST

Longer Lasting Pain Relief

12 HOURS of pain relief

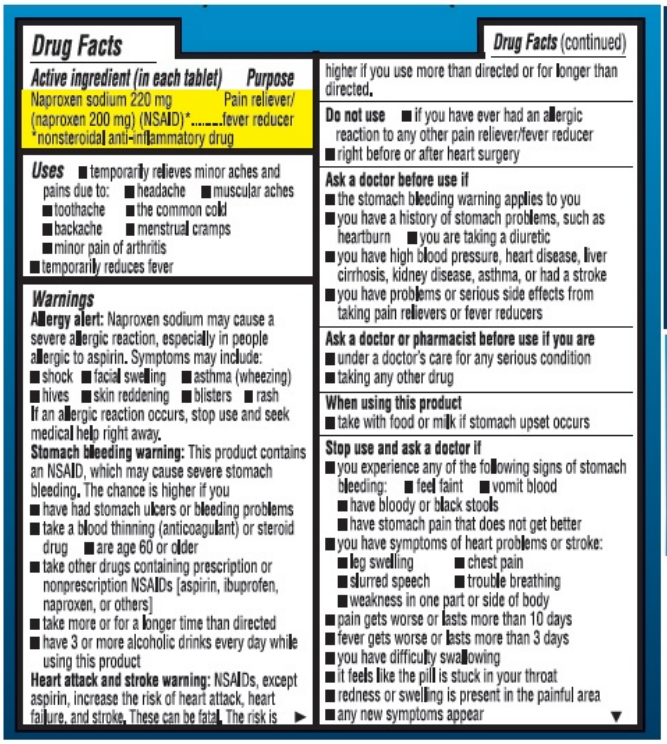
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Distributed by Belmora LLC, 2011 Crystal Dr.#400 Arlington, VA 22202
www.flanaxusa.com

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

Packaging

DRUG FACTS LABEL



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Drug Facts (continued)

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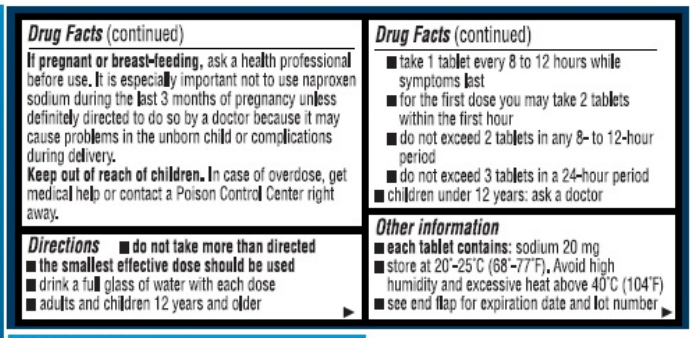

Drug Facts (continued)

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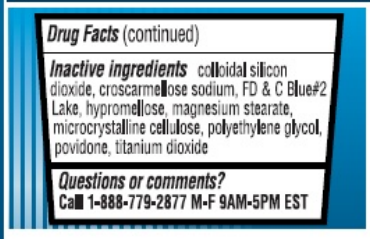

Drug Facts (continued)

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Questions or comments?
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FLANAX PAIN RELIEVER/FEVER REDUCER

naproxen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27854-505
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	144
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:27854-505-01	1 in 1 CARTON	05/15/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:27854-505-02	1 in 1 CARTON	05/15/2020	
2		2 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	05/15/2020	

Labeler - Belmora LLC (112753244)