MENSTRUAL PAIN RELIEVER- naproxen sodium tablet, film coated
Belmora LLC

Flanax 44-604

Active ingredient (in each caplet)

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:
  - toothache
  - muscular aches
  - backache
  - the common cold
  - headache
  - 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:

- asthma (wheezing)
- shock
- facial swelling
- rash
- hives
- skin reddening
- 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
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product

Heart attack and stroke warning: NSAIDs, 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 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

- you are taking a diuretic
- the stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have a history of stomach problems, such as heartburn
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking any other drug
- under a doctor's care for any serious condition

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:
  - have bloody or black stools
  - have stomach pain that does not get better
  - feel faint
  - vomit blood
- 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
- you have difficulty swallowing
- fever gets worse or lasts more than 3 days
- any new symptoms appear
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area

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.

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
- 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

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?

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

Principal display panel

NDC 27854-165-10

FLANAX®

MENSTRUAL
PAIN RELIEVER

Naproxen Sodium Tablets,
220 mg

PAIN RELIEVER/FEVER REDUCER
(NSAID)

10 ι CAPLETS

UP TO 12 HOURS
of menstrual pain relief

WWW.FLANAXUSA.COM

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

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2231 Crystal Dr. #1000
Arlington, VA 22202 www.flanaxusa.com

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MENSTRUAL
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Naproxen Sodium Tablets,
220 mg
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(NSAID)
10 CAPLETS
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Glue Area
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TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
WWW.FLANAXUSA.COM
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No print/No varnish
Lot & Exp date
Drug Facts (continued)
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2231 Crystal Dr. #1000
Arlington, VA 22202
www.flanaxusa.com

Flanax 44-604

MENSTRUAL PAIN RELIEVER

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27854-165
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (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:27854-165-10	1 in 1 CARTON	01/23/2017	
1		10 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	ANDA204872	01/23/2017	

Labeler - Belmora LLC (112753244)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(27854-165)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(27854-165)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(27854-165)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(27854-165)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(27854-165)