

BELMORA FLANAX- naproxen sodium tablet
Belmora LLC

Belmora Flanax

Drug Facts

Active ingredient

Naproxen Sodium USP 220 mg

(naproxen 200 mg) (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains due to:

- backache
- muscular aches
- minor pain of arthritis
- 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

- 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 had 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

- 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, 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 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 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

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

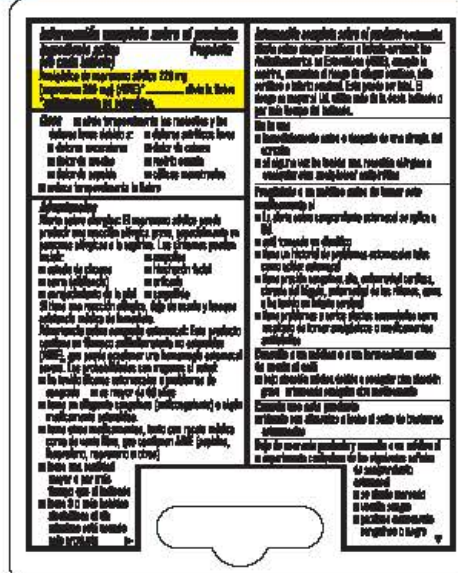
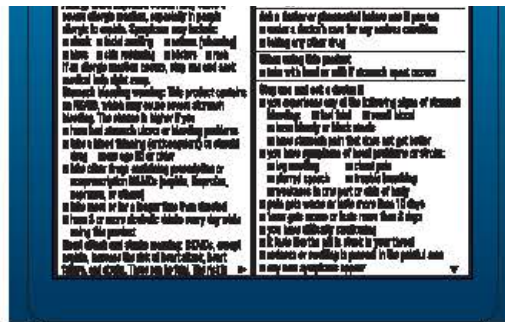
Questions or comments?

1-888-779-2877 M_F 9AM-5PM EST

Drug Facts		Drug Facts (continued)
Active ingredient (in each tablet)	Purpose	
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*	Pain reliever/ fever reducer *nonsteroidal anti-inflammatory drug	
Uses		
- temporarily relieves minor aches and pains 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 redness - blisters - itch 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 a 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, 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 - 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 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	

Drug Facts (continued)
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

Drug Facts (continued)	Drug Facts (continued)
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
	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



Belmora LLC 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

220 mg Tablets Naproxen Sodium USP (NSAID)

FLANAX
PAIN RELIEVER
FEVER REDUCER

Longer Lasting Pain Relief

SEE NEW WARNINGS INFORMATION

Revised April 2020

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Drug Facts (continued)

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Questions or Comments?
Please call 1-888-779-2877 M-F 9AM-5PM EST
Distributed by: Belmora LLC, 2011 Crystal Dr., Suite 400, Arlington, VA 22202 MADE IN INDIA

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-555
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

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:27854-555-02	40 in 1 BOX	07/20/2020	
1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:27854-555-01	1 in 1 CARTON	09/14/2020	
2		24 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	07/20/2020	

Labeler - Belmora LLC (112753244)

Registrant - Belmora LLC (112753244)

Revised: 10/2024

Belmora LLC