

FLANAX- naproxen sodium tablet, film coated
Belmora LLC

Flanax 44-417

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 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:

- 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

- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- 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 at 20 weeks or later in 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 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 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 27854-160-01

Belmora LLC

FLANAX®

Naproxen Sodium Tablets, 220 mg
Pain Reliever/Fever Reducer **(NSAID)**

10 TABLETS

Actual Size

FLANAX®

**Longer Lasting
Pain Relief**

UP TO 12 HOURS of relief

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

Distributed by: Belmora LLC, 3033 Wilson Blvd. #700
Arlington, VA 22201 www.flanaxusa.com

REV1221F41703



FLANAX

PAIN RELIEVER
FEVER REDUCER

Longer Lasting
Pain Relief



PAIN
RELIEVER



FEVER
REDUCER

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NDC 27854-160-01



FLANAX



Naproxen Sodium Tablets, 220 mg
Pain Reliever/Fever Reducer
(NSAID)



Actual Size

10 TABLETS

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c8789r1

Manufactured by: Amgen Inc., 3033 Wilson Blvd, #700
Kenilworth, NJ 07033

Drug Facts (continued)
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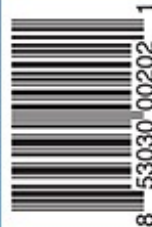
Inactive ingredients *contaminants*
sodium, FDCC, Blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, Tbc, titanium dioxide.

Questions or comments?
Call 1-800-775-2877 M-F 9AM-5PM EST

Drug Facts (continued)
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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 have had stomach ulcers or bleeding problems or for a longer time than directed
• you are taking aspirin or other drugs containing aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs)
• you are age 60 or older
• you have had heart disease, high blood pressure, or have symptoms of heart problems
• you have symptoms of heart problems
• you are taking blood thinners
• you have stomach pain that does not get better
• you have bloody or black stools
• you have signs of stomach bleeding
Stop use and ask a doctor if:
• you experience any of the following:
• you have symptoms of heart problems
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No print/No varnish
Lot & Exp date



Flanax 44-417

FLANAX

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-160
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;417
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-160-01	1 in 1 CARTON	01/15/2018	
1		10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:27854-160-00	1 in 1 CARTON	01/15/2018	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:27854-160-24	1 in 1 CARTON	01/15/2018	
3		24 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	01/15/2018	

Labeler - Belmora LLC (112753244)

Revised: 1/2023

Belmora LLC