

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

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**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 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** colloidal silicon dioxide, FD & C Blue#2 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide, talc

**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

Made in India

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

**Packaging**





## DRUG FACTS LABEL

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Naproxen sodium 220 mg</p> <p><b>Purpose</b> Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>headache</li> <li>muscular aches</li> <li>toothache</li> <li>the common cold</li> <li>backache</li> <li>menstrual cramps</li> <li>minor pain of arthritis</li> </ul> </li> <li>temporarily reduces fever</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> <li>shock</li> <li>facial swelling</li> <li>asthma (wheezing)</li> <li>hives</li> <li>skin redness</li> <li>blisters</li> <li>rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> <li>have had stomach ulcers or bleeding problems</li> <li>take a blood thinning (anticoagulant) or steroid drug</li> <li>are age 60 or older</li> </ul> <p>take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</p> <ul style="list-style-type: none"> <li>take more or for a longer time than directed</li> <li>have 3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is</p>		<p><b>Drug Facts (continued)</b></p> <p>higher if you use more than directed or for longer than directed.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>if you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>right before or after heart surgery</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>the stomach bleeding warning applies to you</li> <li>you have a history of stomach problems, such as heartburn</li> <li>you are taking a diuretic</li> <li>you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>you have problems or serious side effects from taking pain relievers or fever reducers</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>under a doctor's care for any serious condition</li> <li>taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>take with food or milk if stomach upset occurs</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> <li>red or black stools</li> <li>vomiting blood</li> </ul> </li> <li>have bloody or black stools</li> <li>have stomach pain that does not get better</li> <li>you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> <li>leg swelling</li> <li>chest pain</li> <li>slurred speech</li> <li>trouble breathing</li> </ul> </li> <li>weakness in one part or side of body</li> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>you have difficulty swallowing</li> <li>it feels like the pill is stuck in your throat</li> <li>redness or swelling is present in the painful area</li> <li>any new symptoms appear</li> </ul>	
<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>the smallest effective dose should be used</li> <li>drink a full glass of water with each dose</li> <li>adults and children 12 years and older</li> </ul>		<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>each tablet contains: sodium 20 mg</li> <li>store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F)</li> <li>see end flap for expiration date and lot number</li> </ul>	
<p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients:</b> colloidal silicon dioxide, FD &amp; C Blue #2, Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide, talc</p> <p><b>Questions or comments?</b> Call 1-888-779-2877 M-F 9AM-5PM EST</p>			

## FLANAX PAIN RELIEVER/FEVER REDUCER

naproxen sodium tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27854-700
<b>Route of Administration</b>	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)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2910 (5 MPAS) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	blue (light blue)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Circular)	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	J;67
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-700-01	1 in 1 CARTON	05/15/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:27854-700-10	1 in 1 CARTON	05/15/2020	
2		10 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:27854-700-99	1 in 1 CARTON	05/15/2020	
3		100 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	ANDA205497	05/15/2020	

**Labeler** - Belmora LLC (112753244)