

## **NAPROXEN SODIUM- naproxen sodium tablet**

**Kinray**

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### **Drug Facts**

#### **Active ingredient (in each caplet)**

Naproxen sodium, USP 220 mg (naproxen 200 mg) (NSAID)\*\*

\*\*nonsteroidal anti-inflammatory drug

#### **Purposes**

Pain reliever/ fever reducer

#### **Uses**

- temporarily relieves minor aches and pain due to:
- minor pain of arthritis
- muscular aches
- backache
- 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 thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time 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 have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

### **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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

### **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
- 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. (1-800-222-1222)

### **Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

- |   |
|---|
| <ul style="list-style-type: none"><li>• take 1 caplet every 8 to 12 hours while symptoms last</li><li>• for the first dose you may take 2 caplets within the first hour</li></ul> |
|---|

Adults and children 12 years and older	<ul style="list-style-type: none"> <li>do not exceed 2 caplets in any 8 to 12 hour period</li> <li>do not exceed 3 caplets in a 24-hour period</li> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li>ask a doctor</li> </ul>

**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)

**Inactive Ingredients:**

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

**Questions or comments? 1-877-586-7979**

**PRINCIPAL DISPLAY PANEL - 220 mg TABLET CARTON**

□

Preferred Plus Pharmacy

NDC 61715-060-50

SEE NEW WARNINGS INFORMATION

\*Compare to the Active Ingredient in Aleve®

Naproxen Sodium Tablets, USP 220 mg

Pain Reliever/Fever Reducer (NSAID)

50 COATED CAPLETS†

†CAPSULE-SHAPED TABLETS

Distributed By:

Kinray, Inc., Whitestone, NY 11357

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# NAPROXEN SODIUM

naproxen sodium tablet

## Product Information

LEBG609A

LOT NO. 3  
EXP. 45738 31150 0

NIN # 400317

Distributed By: Kerry, Inc., Whippany, NJ 1337  
Made in the USA

All Preferred Plus Pharmacy products are  
satisfaction guaranteed or your money back from  
retailer where purchased.

NDC 61715-060-50

Compare to the Active Ingredient in Aleve®

**SEE NEW WARNINGS INFORMATION**

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

50 Caplets! Capsule-Shaped Tablets

**687**  
**Questions or comments? (877) 586-7878**

**Drug Facts (continued)**

- 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. (1-800-222-1222)

**Directions** ■ do not take more than directed  
■ the smallest effective dose should be used  
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- 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)

**Important: Read all product information before using. Keep this box for important information.**

**Do not use if seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing**

**Drug Facts**

**Active ingredient (in each caplet)**  
Naproxen sodium, USP 220 mg Pain reliever/fever reducer  
(naproxen 200 mg)(NSAID)\*  
\*nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - backache
  - toothache
  - temporarily reduces fever
- menstrual cramps
- the common cold

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- stomach pain
- itchy skin
- dizziness
- asthma (wheezing)
- 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 65 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug

**Drug Facts (continued)**

- 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

**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**

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- you have a history of stomach problems, such as heartburn
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- you are taking a diuretic
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Rev. 04/13

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 1715-060	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y6R9ATQ)	NAPROXEN SODIUM	220 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
	FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
	POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	POLYVINYL ALCOHOL (UNII: 532B59J990)			
	POVIDONE (UNII: FZ989GH94E)			
	STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
	TALC (UNII: 7SEV7J4R1U)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
<b>Product Characteristics</b>				
<b>Color</b>	blue	<b>Score</b>	no score	
<b>Shape</b>	OVAL (Capsule-Shaped)	<b>Size</b>	12mm	
<b>Flavor</b>		<b>Imprint Code</b>	17	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:6 1715-060-50	1 in 1 CARTON		
1		50 in 1 BOTTLE, PLASTIC		
2	NDC:6 1715-060-51	1 in 1 CARTON		
2		100 in 1 BOTTLE, PLASTIC		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA079096	11/25/2009		

**Labeler** - Kinray (012574513)

**Registrant** - Aphenia Pharma Solutions - Kentucky, LLC (557054835)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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Aphena Pharma Solutions - Kentucky, LLC		557054835	repack(61715-060)
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## Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals		831227801	manufacture(61715-060)

Revised: 5/2013

Kinray