

# **ALL DAY PAIN RELIEF- naproxen sodium tablet H E B**

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## **Drug Facts**

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

**Naproxen sodium 220 mg**

**(naproxen 200 mg) (NSAID)\***

**\*nonsteroidal anti-inflammatory drug**

## **Purposes**

**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 thinning (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:** 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 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 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:
  - have bloody or black stools
  - feel faint
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - slurred speech
  - leg swelling
  - 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 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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). Protect from light.

**Inactive ingredients**

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

**Questions or comments?**

Call toll free: **1-877-753-3935** Monday-Friday 9AM-5PM EST

**Principal Display Panel**

Compare to Aleve® active ingredient\*\*

**Naproxen Sodium**

Tablets, (**NSAID**) 220 mg

Pain Reliever / Fever Reducer

Strength To Last 12 Hours

CAPLETS†

(†Capsule-Shaped Tablets)

\*\*This product is not manufactured or distributed by Bayer HealthCare LLC., distributor of Aleve.

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

## Product Label

Drug Facts	
<b>Active ingredient</b> (in each caplet) Naproxen sodium USP, 220 mg (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug	<b>Purposes</b> Pain reliever/ fever reducer
<b>Uses</b> ■ 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	
<b>Warnings</b> <b>Allergy alert:</b> 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. <b>Stomach bleeding warning:</b> 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 every day while using this product ■ take more or for a longer time than directed <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 higher if you use more than directed or for longer than directed.	

Drug Facts (continued)	
<b>Do not use</b> ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery	
<b>Ask a doctor before use if</b> ■ 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	
<b>Ask a doctor or pharmacist before use if you are</b> ■ 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	
<b>When using this product</b> ■ take with food or milk if stomach upset occurs	
<b>Stop use and ask a doctor if</b> ■ you experience any of the following signs of stomach bleeding: ■ have bloody or black stools ■ feel faint ■ vomit blood ■ have stomach pain that does not get better ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ slurred speech ■ leg swelling ■ 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	
<b>If pregnant or breast-feeding,</b> ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless	

Drug Facts (continued)	
definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b> ■ 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	
<b>Other information</b> ■ each caplet contains: sodium 20 mg ■ store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). Protect from light.	
<b>Inactive ingredients</b> croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide	
<b>Questions or comments?</b> Call toll free: 1-877-753-3935 Monday-Friday 9AM-5PM EST *This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Aleve®.	

**Compare to Aleve®**  
active ingredient\*\*

NDC 37808-068-24

**H-E-B®**

**Naproxen Sodium**

Tablets, (**NSAID**) 220 mg

**Pain Reliever/Fever Reducer**

**Strength To Last 12 Hours**

**24 CAPLETS\***  
(Capsule-Shaped Tablets)

actual size

MADE WITH PRIDE AND CARE FOR H-E-B®,  
SAN ANTONIO, TX 78204 Product of India

**100% GUARANTEE**  
promise

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

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FC008425 PLD-E115K

Lot No.:  
Exp. Date:

**H-E-B Naproxen Sodium 220 mg Tablets**

# ALL DAY PAIN RELIEF

naproxen sodium tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-068
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NAPROXEN SODIUM</b> (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	I7
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37808-068-24	1 in 1 BOX	09/30/2015	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:37808-068-50	1 in 1 BOX	09/30/2015	
2		50 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	ANDA079096	09/30/2015	

**Labeler -** H E B (007924756)

Revised: 12/2023

H E B