

**BACK AND MUSCLE PAIN- naproxen sodium tablet, film coated**  
**CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS 44-417BackandMuscle**

***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:
  - backache
  - muscular aches
  - the common cold
  - toothache
  - headache
  - 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)
- skin reddening
- shock
- blisters
- rash
- facial swelling
- hives

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 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 1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

### ***Principal display panel***

**CVS  
Health®**

Compare to the active ingredient  
in Aleve® Back & Muscle Pain†

Tablets

**Back &  
Muscle**

## **Pain**

NAPROXEN SODIUM  
TABLETS, 220 mg

Pain reliever,  
Fever reducer  
**(NSAID)**

RELIEVES  
BACK &  
MUSCLE PAIN

Actual  
Size

**24** TABLETS

STRENGTH  
TO LAST  
**12**  
HOURS

100% money back  
guaranteed.  
[CVS.com/returnpolicy](https://www.cvs.com/returnpolicy)

†This product is not manufactured or distributed  
by Bayer HealthCare LLC, owner of the registered  
trademark Aleve® Back & Muscle Pain.  
50844 REV1221C41708

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



CVS 44-417BM

## BACK AND MUSCLE PAIN

naproxen sodium tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-817
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2--ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<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>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;417
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-817-52	1 in 1 CARTON	04/18/2022	
1		90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:51316-817-08	1 in 1 CARTON	04/18/2022	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:51316-817-15	1 in 1 CARTON	04/18/2022	08/08/2024
3		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	ANDA204872	04/18/2022	

**Labeler** - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(51316-817)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-817)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-817)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(51316-817)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-817)

Revised: 5/2023

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