

**NAPROXEN SODIUM- naproxen sodium tablet, film coated**  
**Meijer Distribution Inc**

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**Meijer Distribution, Inc. Naproxen Sodium Tablets, 220 mg Drug Facts**

**Active ingredient (in each tablet)**

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:
- 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 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:
- 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:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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
- 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 22 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

### **Inactive ingredients**

FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

### **Questions or comments?**

**1-800-719-9260**

### **Principal Display Panel**

Compare to Aleve® active ingredient  
 naproxen sodium Tablets, 220 mg  
 STRENGTH TO LAST 12 HOURS  
 Pain Reliever  
 Fever Reducer  
 (NSAID)  
 50 Tablets  
 actual size



**Drug Facts (continued)**

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:  chest pain  trouble breathing  weakness in one part or side of body  slurred speech  leg swelling  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.

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**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 22 mg  store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Drug Facts (continued)**

**Inactive ingredients** FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-719-9260

**KEEP CARTON FOR REFERENCE**

**DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING**

**meijer** NDC 41250-680-71  
**naproxen sodium**  
 Tablets, 220 mg  
**STRENGTH TO LAST 12 HOURS** Pain Reliever  
 Fever Reducer (NSAID)  
 50 Tablets  
 actual size

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**GF**  
 GLUTEN FREE

Discard Seal, Empty & Reclose Cap  
 PAPER BOX PLASTIC BOTTLE  
 how2recycle.info

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**meijer** NDC 41250-680-71  
 Compare to Aleve® active ingredient™

**naproxen sodium**  
 Tablets, 220 mg  
**STRENGTH TO LAST 12 HOURS** Pain Reliever  
 Fever Reducer (NSAID)  
 50 Tablets  
 actual size

**49071 6E C18**

**Drug Facts**

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

**Uses**  temporarily relieves minor aches and pains 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 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

naproxen sodium tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-680
<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>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE (Light Blue)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L490
<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:41250-680-71	1 in 1 CARTON	03/05/2014	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41250-680-78	1 in 1 CARTON	03/05/2014	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41250-680-75	1 in 1 CARTON	02/14/2022	
3		90 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA074661	03/05/2014	

**Labeler** - Meijer Distribution Inc (006959555)

Revised: 2/2022

Meijer Distribution Inc