

**CALMADOL PAIN RELIEVER- naproxen sodium tablet**  
**Grandall Distributing Co., Inc.**

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**CALMADOL PAIN RELIEVER Tablets, 24 count**

**Active Ingredients (in each tablet)**

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

**Purpose**

Pain reliever/  
fever reducer

**Uses**

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

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.

**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 ■ 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

- 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

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 problems or serious side effects from taking pain relievers or fever reducers
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- 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

## **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). Keep Carton.

**Questions**

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Distributed by: Grandall Distributing Co., Inc. Glendale, CA 91204-2707

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline, cellulose, polyethylene glycol, povidone, titanium dioxide

**Package Labeling**

CALMADOL

PAIN RELIEVER

FEVER REDUCER

Naproxen Sodium Tablets

220 mg (NSAID)

24 TABLETS

**Analgésico**  
**CALMADOL®**  
PAIN RELIEVER  
FEVER REDUCER

**Alivia Dolor**  
**Pain Relief**

Naproxeno Sódico Tabletas  
220 mg (NSAID)  
Naproxen Sodium Tablets  
220 mg (NSAID)

**24** TABLETAS  
TABLETS

SEALED WITH PRINTED FOIL UNDER CAP

THIS LABEL DOES NOT CONTAIN FULL PRODUCT INFORMATION. SEE CARTON FOR COMPLETE INFORMATION. READ ALL WARNING AND DIRECTIONS ON CARTON BEFORE USE. RETAIN CARTON FOR REFERENCE.

**Active Ingredient (in each tablet)**

Naproxen sodium 220 mg.....Pain reliever/  
(naproxen 200 mg)(NSAID)\* fever reducer

\*nonsteroidal anti-inflammatory drug

**Purposes**

**Uses:** temporarily relieves minor aches and pains due to:

- headache ■ muscular aches ■ minor pain of arthritis
- backache ■ the common cold ■ menstrual cramps
- toothache ■ temporarily reduces fever

**Directions:** Do not take more than directed. The smallest effective dose should be used. Do not take longer than 10 days, unless directed by a doctor (see Warnings on carton). 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.

**Adults over 65 years:** Do not take more than 1 tablet every 12 hours unless directed by a doctor

**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). Keep Carton.

**Questions:** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

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Grandall Distributing Co., Inc.  
Glendale, CA 91204-2707

Do not varnish  
this yellow area.  
To be used for Date Stamp

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>				
<b>Active ingredient (in each tablet)</b> Naproxen sodium 220 mg (naproxen 200 mg)(NSAID)* <small>*nonsteroidal anti-inflammatory drug</small>	<b>Purposes</b> Pain reliever/fever reducer	<b>Ask a doctor before use if</b> <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               <ul style="list-style-type: none"> <li>you have high blood pressure, heart disease, liver cirrhosis, or kidney disease</li> <li>you are taking a diuretic</li> </ul> </li> <li>you have problems or serious side effects from taking pain relievers or fever reducers</li> <li>you have asthma</li> </ul>				
<b>Uses</b> <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>minor pain of arthritis</li> <li>temporarily reduces fever</li> </ul> </li> <li>backache</li> <li>the common cold</li> <li>menstrual cramps</li> </ul>	<b>Warnings</b> <b>Allergy alert:</b> Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> <li>hives</li> <li>skin reddening</li> <li>shock</li> <li>asthma (wheezing)</li> <li>facial swelling</li> <li>rash</li> <li>blisters</li> </ul> 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: <ul style="list-style-type: none"> <li>are age 60 or older</li> <li>have had stomach ulcers or bleeding problems</li> <li>take a blood thinning (anticoagulant) or steroid drug</li> <li>take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>have 3 or more alcoholic drinks every day while using this product</li> <li>take more or for a longer time than directed</li> </ul> <b>Do not use</b> <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>	<b>Ask a doctor or pharmacist before use if you are</b> <ul style="list-style-type: none"> <li>under a doctor's care for any serious condition</li> <li>taking any other drug</li> </ul> <b>When using this product</b> <ul style="list-style-type: none"> <li>take with food or milk if stomach upset occurs</li> <li>the risk of heart attack or stroke may increase if you use more than directed or for longer than directed</li> </ul> <b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>side effects occur. You may report side effects to FDA at 1-800-FDA-1088.</li> <li>you experience any of the following signs of stomach bleeding:               <ul style="list-style-type: none"> <li>feel faint</li> <li>vomit blood</li> <li>have bloody or black stools</li> <li>have stomach pain that does not get better</li> </ul> </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> <b>If pregnant or breast-feeding,</b> 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. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.				
<b>Levanta la tapa posterior para ver los Información sobre el Medicamento en Español</b>						
<b>Drug Facts (continued)</b> <b>Directions</b> <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> </ul> <table border="1"> <thead> <tr> <th>Adults and children 12 years and older</th> <th>Children under 12 years</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> <li>take 1 tablet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 tablets within the first hour</li> <li>do not exceed 2 tablets in any 8 to 12 hour period</li> <li>do not exceed 3 tablets in a 24-hour period</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>ask a doctor</li> </ul> </td> </tr> </tbody> </table>			Adults and children 12 years and older	Children under 12 years	<ul style="list-style-type: none"> <li>take 1 tablet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 tablets within the first hour</li> <li>do not exceed 2 tablets in any 8 to 12 hour period</li> <li>do not exceed 3 tablets in a 24-hour period</li> </ul>	<ul style="list-style-type: none"> <li>ask a doctor</li> </ul>
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<b>Other information</b> <ul style="list-style-type: none"> <li>each tablet contains: sodium 20 mg</li> <li>store at 20 to 25 °C (68 to 77 °F). Avoid high humidity and excessive heat above 40 °C (104 °F).</li> <li>tamper-evident: do not use if the imprinted seal under the cap is broken or missing.</li> </ul>						
<b>Inactive ingredients</b> colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide						

## CALMADOL PAIN RELIEVER

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:48201-007
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)		NAPROXEN SODIUM	220 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
<b>Product Characteristics</b>				
<b>Color</b>	blue	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	10mm	
<b>Flavor</b>		<b>Imprint Code</b>	141	
<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:48201-007-24	1 in 1 BOX	03/31/2015	
1		24 in 1 PACKET; Type 0: Not a Combination Product		
<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	ANDA090545	03/31/2015		

**Labeler** - Grandall Distributing Co., Inc. (044428324)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Weeks & Leo Co., Inc.		005290028	repack(48201-007)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MARKSANS PHARMA LIMITED		925822975	manufacture(48201-007)