

**GOOD SENSE ALL DAY PAIN RELIEF- naproxen sodium tablet**  
**Aidarex Pharmaceuticals LLC**

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**Perrigo All Day Pain Relief Drug Facts**

**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:
- 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

**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

Adults and	<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></ul>
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children 12 years and older	<ul style="list-style-type: none"> <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>
Children under 12 years	ask a doctor

**Other information**

- each tablet contains: sodium 21 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**

Strength to Last 12 Hours

See New Warnings Information

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever & Fever Reducer (NSAID)

Actual Size

Compare to active ingredient of Aleve® Tablets

Repackaged By :

Aidarex Pharmaceuticals LLC,  
Corona, CA 92880

## GOOD SENSE ALL DAY PAIN RELIEF

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:33261-079(NDC:0113-9490)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (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>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:33261-079-28	28 in 1 BOTTLE, PLASTIC		
2	NDC:33261-079-30	30 in 1 BOTTLE, PLASTIC		
3	NDC:33261-079-40	40 in 1 BOTTLE, PLASTIC		

### 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	01/14/1997	

