# KIRKLAND SIGNATURE NAPROXEN SODIUM- naproxen sodium tablet, film coated Costco Wholesale Company

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# Costco Wholesale Corp. Naproxen Sodium Tablets USP, 220 mg 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:
- 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 children 12 years and older	<ul> <li>take 1 caplet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 caplets within the first hour</li> <li>do not exceed 2 caplets in any 8- to 12-hour period</li> <li>do not exceed 3 caplets in a 24-hour period</li> </ul>
Children under 12 years	• ask a doctor

## Other information

- each caplet 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**

COMPARE TO ALEVE® active ingredient

STRENGTH TO LAST 12 HOURS

NAPROXEN SODIUM Tablets USP, 220 mg

Pain Reliever/Fever Reducer (NSAID)

**Actual Size** 

400 Caplets†

†capsule shaped tablets



#### KIRKLAND SIGNATURE NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:63981-368
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NAPRO XEN SO DIUM (NAPRO XEN)	NAPROXEN SODIUM	220 mg

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSES	
MAGNESIUM STEARATE	
CELLULO SE, MICRO CRYSTALLINE	
POLYETHYLENE GLYCOLS	
POVIDONES	
TALC	
TITANIUM DIO XIDE	

Product Cha	aracteristics		
Color	BLUE (Light Blue)	Score	no score
Shape	CAPSULE (oval)	Size	12mm
Flavor		Imprint Code	L368
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63981-368-79	400 in 1 BOTTLE		
3.5 1 .1 T.C	.•		
Marketing Info	rmation		
Marketing Info Marketing Category	rmation Application Number or Monogra	ph Citation Marketing Start	Date Marketing End Date
		ph Citation Marketing Start 06/04/2007	Date Marketing End Date

# Labeler - Costco Wholesale Company (103391843)

Revised: 12/2013 Costco Wholesale Company