HEALTHY ACCENTS NAPROXEN SODIUM- naproxen sodium tablet, film coated DZA Brands LLC

DZA Brands, LLC Naproxen Sodium Tablets, 220mg 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:

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

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?

1-866-322-2439

Principal Display Panel

Compare to Aleve® Caplets active ingredient strength to last 12 Hours naproxen sodium tablets, 220mg pain reliever - fever reducer (NSAID) actual size 50 caplets**



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Drug Facts

Active ingredient (in each caplet) Purposes Pain reliever/ Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*.....fever reducer

*nonsteroidal anti-inflammatory drug

Uses temporarily relieves minor aches and pains due to: ■ min or pain of arthritis ■ muscular aches ■ backache menstrual cramps headache ■ toothache

the common cold

temporarily reduces fever

Warnings

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■ hives ■ facial swelling ■ asthma (wheezing)

shock ■ skin reddening ■ rash ■ blisters If an allergic reaction occurs, stop use and seek medical help right away.

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■ 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 In 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

Drug Facts (continued)

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
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HEALTHY ACCENTS NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55316-699	
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 Characteristics			
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:55316-699-71	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:55316-699-78	1 in 1 CARTON		
2		100 in 1 BOTTLE		
3	NDC:55316-699-62	1 in 1 CARTON		
3		24 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074661	01/22/2008		

Labeler - DZA Brands LLC (090322194)

Revised: 12/2013 DZA Brands LLC