

ALL DAY PAIN RELIEF- naproxen sodium tablet

Freds Inc

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

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
- you develop heartburn
- 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 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- Read all warnings and directions before use. Keep carton.

Inactive ingredients

croscarmellose sodium, FD & C Blue # 2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc and titanium dioxide.

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

All Day Pain Relief

Naproxen sodium tablets

Pain reliever/fever reducer (NSAID)

Tablets

220 mg each

Compare to the active ingredient in: Aleve®†

†This product is not manufactured or distributed by Bayer Healthcare, LLC, owner of the registered trademark Aleve®

DO NOT USE IF INNER SEAL UNDER BOTTLE CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: fred's Inc

4300 NEW GETWELL RD, MEMPHIS , TN, 38118

www.fredsinc.com

Package Label

8 0 84579 53441 1
PLD-C116E
F0003049
Lot No.:
Exp. Date:

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Drug Facts (continued)

- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
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Drug Facts (continued)

nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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Drug Facts (continued)

Inactive ingredients
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4300 NEW GETWELL RD, MEMPHIS, TN 38118
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100% satisfaction guaranteed

Questions or comments:
1-855-331-FRED (3733)

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Nonsteroidal anti-inflammatory drug

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- take other drugs containing prescription or



NDC 55315-169-24

ACTUAL SIZE

ALL DAY PAIN RELIEF

Naproxen Sodium Tablets, 220 mg

Pain Reliever/Fever Reducer (NSAID)

24 TABLETS
220 MG EACH

Compare to the active ingredient in:
Aleve®†

COATING
FREE AREA


880494



Fred's All Day Pain Relief Tablets

ALL DAY PAIN RELIEF naproxen sodium tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-169
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	13
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-169-24	1 in 1 BOX	09/30/2015	04/26/2024
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	09/30/2015	04/26/2024

Labeler - Freds Inc (005866116)