NAPROXEN SODIUM- naproxen sodium tablet FREDS INC

ALL DAY PAIN RELIEF

Naproxen Sodium Tablets, USP 220 mg

Active ingredient (in each tablet)

Active ingredient (in each caplet)

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

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 the reach of children

In case of overdose, get medical help or contact a Poison Control Center right away

Directions

for Tablets

- 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

For Caplets

- 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 tablets contains: sodium 20 mg
- store at 20 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD&C blue #2 aluminum lake, hypromellose, maize starch, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

ALL DAY PAIN RELIEF

1-877-770-3183 Mon-Fri 9:00 AM to 4:00 PM EST

Naproxen Sodium Tablets, USP 220 mg Pain Reliever/Fever Reducer (NSAID) GLUTEN-FREE

STRENGTH TO LAST 12 HOURS

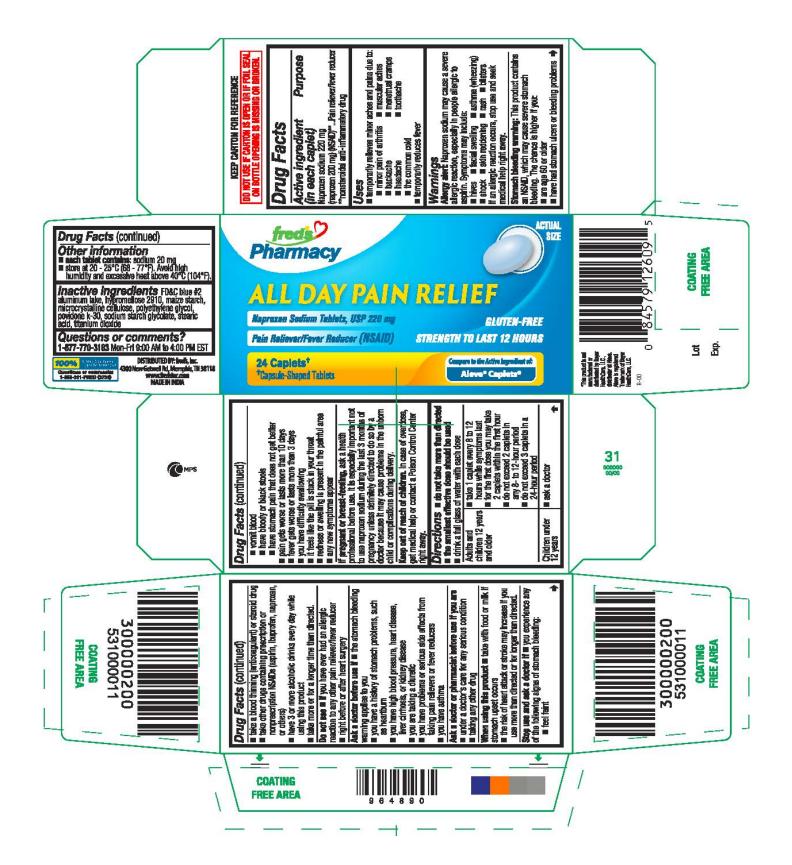
24 Tablets



ALL DAY PAIN RELIEF

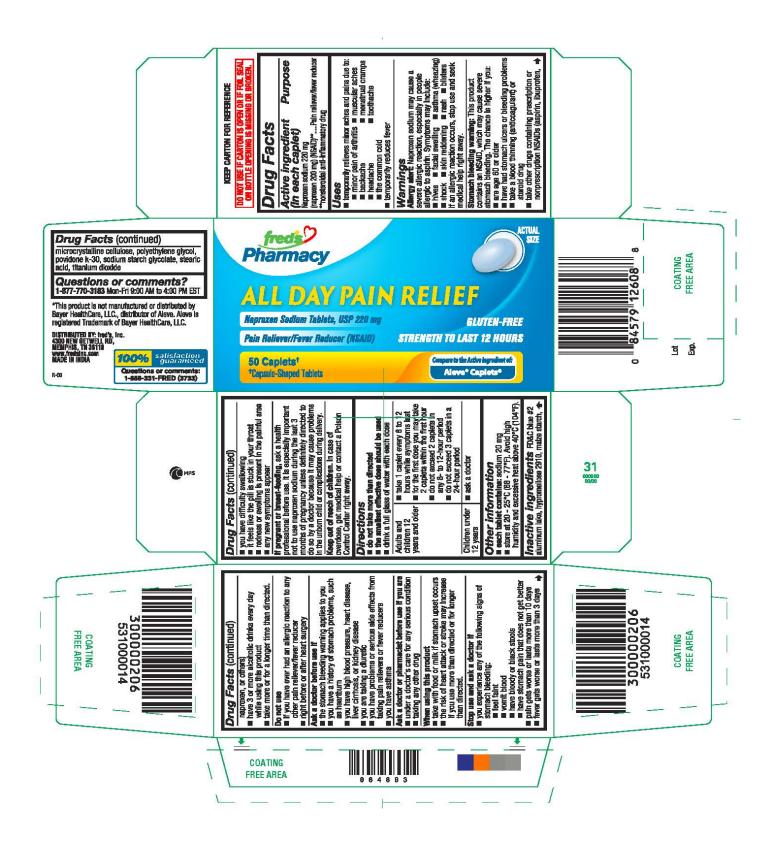
Naproxen Sodium Tablets, USP 220 mg GLUTEN-FREE Pain Reliever/Fever Reducer (NSAID) STRENGTH TO LAST 12 HOURS 24 Caplets+

+ Capsule-Shaped Tablets



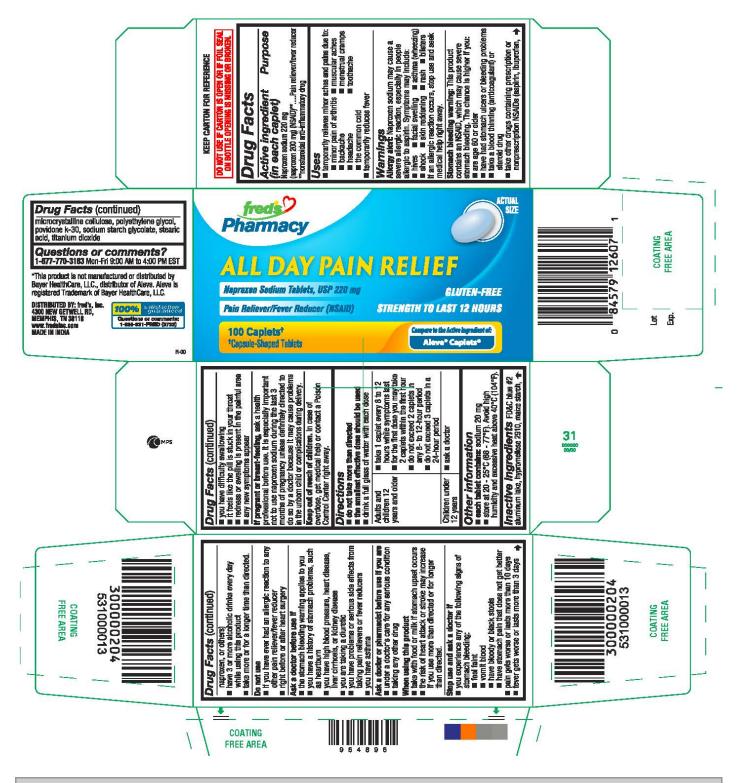
ALL DAY PAIN RELIEF
Naproxen Sodium Tablets, USP 220 mg
GLUTEN-FREE
Pain Reliever/Fever Reducer (NSAID)
STRENGTH TO LAST 12 HOURS
50 Caplets+

+ Capsule-Shaped Tablets



ALL DAY PAIN RELIEF
Naproxen Sodium Tablets, USP 220 mg
GLUTEN-FREE
Pain Reliever/Fever Reducer (NSAID)
STRENGTH TO LAST 12 HOURS
100 Caplets+

+ Capsule-Shaped Tablets



NAPROXEN SODIUM

naproxen sodium tablet

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55315-992 Route of Administration ORAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	NAPRO XEN SO DIUM (UNII: 9TN87S3A3C) (NAPRO XEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
PO VIDONE K30 (UNII: U725QWY32X)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
STARCH, CORN (UNII: O8232NY3SJ)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	220	
Contains				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55315-992-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017			
2	NDC:55315-992-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017			
3	NDC:55315-992-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091353	08/17/2017		

NAPROXEN SODIUM

naproxen sodium tablet

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Route of Administration	ORAL		

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Inactive Ingredients				
Ingredient Name	Strength			
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TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
STARCH, CORN (UNII: O8232NY3SJ)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
PO VIDO NE K30 (UNII: U725QWY32X)				

Product Characteristics			
Color	blue	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	I1
Contains			

ı	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:55315-991-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091353	08/17/2017		

Labeler - FREDS INC (005866116)

Revised: 7/2017 FREDS INC