ALL DAY PAIN RELIEF- naproxen sodium tablet
Freds Inc

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:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - backache
  - the common cold
  - menstrual cramps
- 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

- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- 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 have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma
- you are taking a diuretic

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
  - have bloody or black stools
  - vomit blood
  - 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
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

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.

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 20 mg**
- store at 20° to 25°C (68° to 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, 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, 220 mg

Pain Reliever / Fever Reducer **(NSAID)**

CAPLETS**

(**Capsule-Shaped 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

Product Label

Fred's All Day Pain Relief Caplets

ALL DAY PAIN RELIEF

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-168
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: 3WQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-168-50	1 in 1 BOX	09/30/2015	04/26/2024
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55315-168-01	1 in 1 BOX	09/30/2015	04/26/2024
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:55315-168-24	1 in 1 BOX	09/30/2015	04/26/2024
3		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA079096	09/30/2015	04/26/2024

Labeler - Freds Inc (005866116)

Revised: 10/2021 Freds Inc