PAIN RELIEF- naproxen sodium tablet, film coated
Gobrands, Inc

Pain Relief

Naproxen Sodium

Drug Facts

Active Ingredient (in each tablet)

Naproxen Sodium 220 mg**

**nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- backache n headache n menstrual cramps
- minor pain of arthritis n muscular aches
- the common cold n toothache
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin.
Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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

Heart attack and stroke warning: NSAIDs, except aspirin increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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 you
- 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, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are if you are
- under a doctor's care for any serious condition
- taking any other drug
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin

When using this product
- take with food or milk if stomach upset occurs

Stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding: n feel faint n vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech n leg swelling
- 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 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 between 20˚-25˚C (68˚-77˚F). Avoid high humidity and excessive heat above 40˚C (104˚F)

Inactive ingredients

Microcrystalline cellulose, Starch, Sodium starch glycolate, povidone (K-30), stearic acid, purified water, hydroxy propyl methylcellulose, polyethylene glycol, titanium dioxide, FD&C Blue #2 aluminum lake

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Aleve

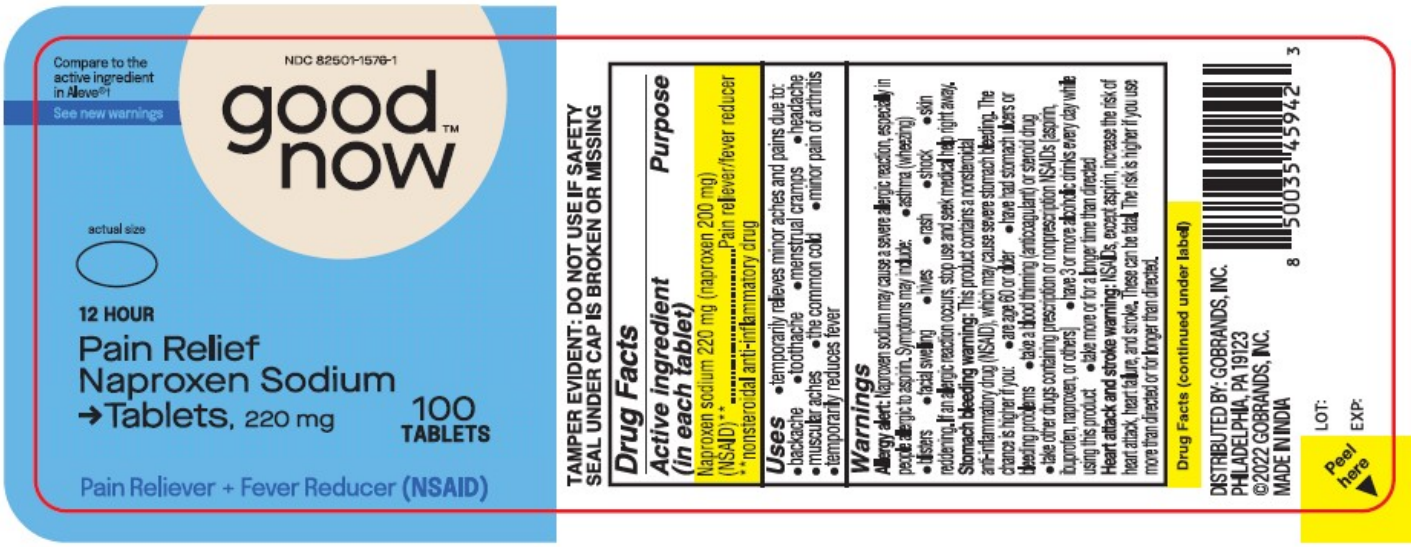
NDC 82501-1576-1

Good now

12 HOUR
Pain Relief
Naproxen Sodium Tablets, 220 mg

100 TABLETS

Pain Reliever + Fever Reducer (NSAID)



PAIN RELIEF

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82501-1576
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, POTATO (UNII: 8I089SAH3T)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82501-1576-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	05/30/2022	

Labeler - Gobrands, Inc (057499049)

Revised: 12/2023 Gobrands, Inc