NAPROXEN SODIUM- naproxen sodium tablet, film coated, extended release
SPIRIT PHARMACEUTICALS,LLC

NAPROXEN SODIUM TABLETS, USP 220 mg

Drug Facts

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Pain reliever/

fever reducer

Uses

- temporarily relieves minor aches and pain due to :
- backache
- headache
- menstrul cramps
- minor pain of arthritis
- muscular aches
- the common cold
- 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 non steroidal 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

NSAID's except aspirin increases 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 surgery

Ask a doctor before use if
- the stomach bleeding warning applies to you
- you have a history of stomach problems,such as a heartburn
- you have a high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have problems or serious side effects 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 conditions
- 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 following sign 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 feel 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 profession 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 complication during the delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a position 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 one tablet every 8 to 12 hours while symptoms last • for the first dose you may take within the first hour • do not exceed 2 tablets in any 8 to 12 hours period • do not exceed 3 tablets in 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

Colloidal silicon dioxide*, croscarmellose sodium*, FD&C Blue#2 lake, hypromellose, magnesium stearate*, maize starch*, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate*, stearic acid*, titanium dioxide.

*contains one or more of these ingredients

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

CABINET

NAPROXEN SODIUM TABLETS, USP 220 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

NAPROXEN SODIUM

naproxen sodium tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4096
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**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	220

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4096-1	365 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	07/02/2020	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

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