NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
PuraCap Pharmaceutical LLC

Naproxen Sodium Capsules, 220 mg

Drug Facts

Active ingredient (in each capsule)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

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

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
- 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
- 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

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
  - you have symptoms of heart problems or stroke:
    - chest pain
    - trouble breathing
    - weakness in one part or side of body
    - slurred speech
    - leg swelling
- 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 capsule 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
- if taken with food, this product may take longer to work

adults and children 12 years and older:	• take 1 capsule every 8 to 12 hours while symptoms last • for the first dose you may take 2 capsules within the first hour • do not exceed 2 capsules in any 8- to 12-hour period • do not exceed 3 capsules in a 24-hour period
children under 12 years:	• ask a doctor

Other information

- **each capsule 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 directions and warnings before use. Keep carton.

Inactive ingredients

FD&C blue#1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide, white ink

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

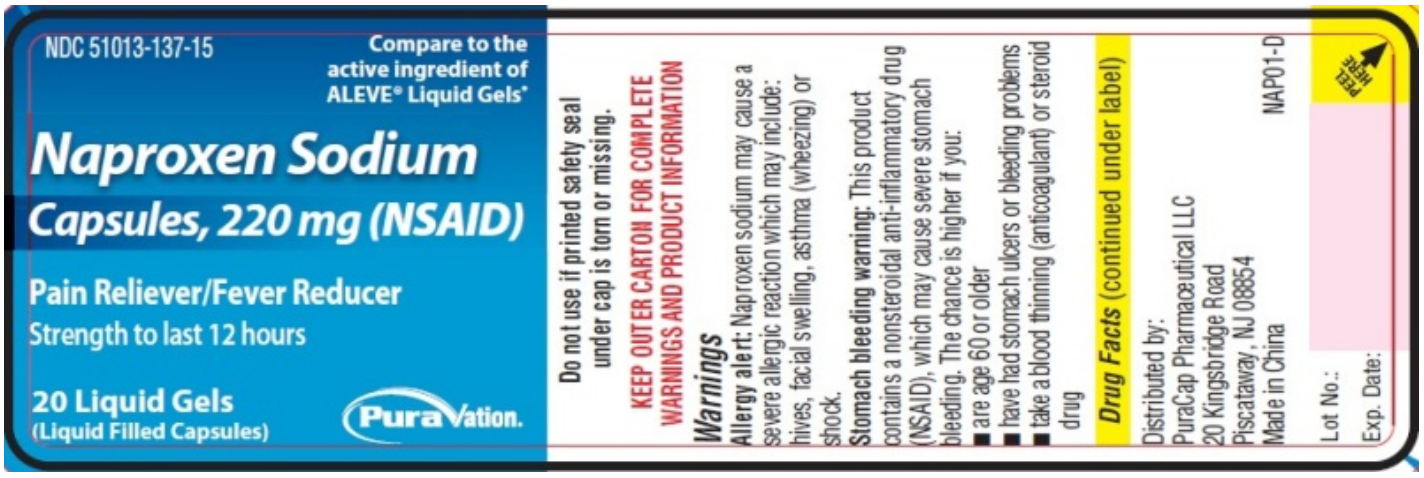
Naproxen Sodium Capsules, 220 mg (NSAID)

pain reliever/fever reducer

NDC 51013-137-15

20 LIQUID GELS (LIQUID FILLED CAPSULES)


NDC 51013-137-15
Compare to the active ingredient of ALEVE® Liquid Gels*
Naproxen Sodium
Capsules, 220 mg (NAIID)
Pain Reliever/Fever Reducer
Strength to last 12 hours
20 Liquid Gels (Liquid Filled Capsules)
PuraVation.
Do not use if printed safety seal under cap is torn or missing.
Drug Facts
Active ingredient (in each capsule)
Purposes
Uses
Warnings
Drug Facts (continued)
Directions
Other information
Inactive ingredients
Questions or comments?
Call toll free: 1-855-215-5168
*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of ALEVE® Liquid Gels.
NAP02-D


NDC 51013-137-15
Compare to the active ingredient of ALEVE® Liquid Gels*
Naproxen Sodium
Capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer
Strength to last 12 hours
20 Liquid Gels
(Liquid Filled Capsules)
PuraVation.
Do not use if printed safety seal under cap is torn or missing.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION
Warnings
Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing) or shock.
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
Drug Facts (continued under label)
Distributed by:
PuraCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854
Made in China
NAP01-D
PEEL HERE
Lot No.:
Exp. Date:

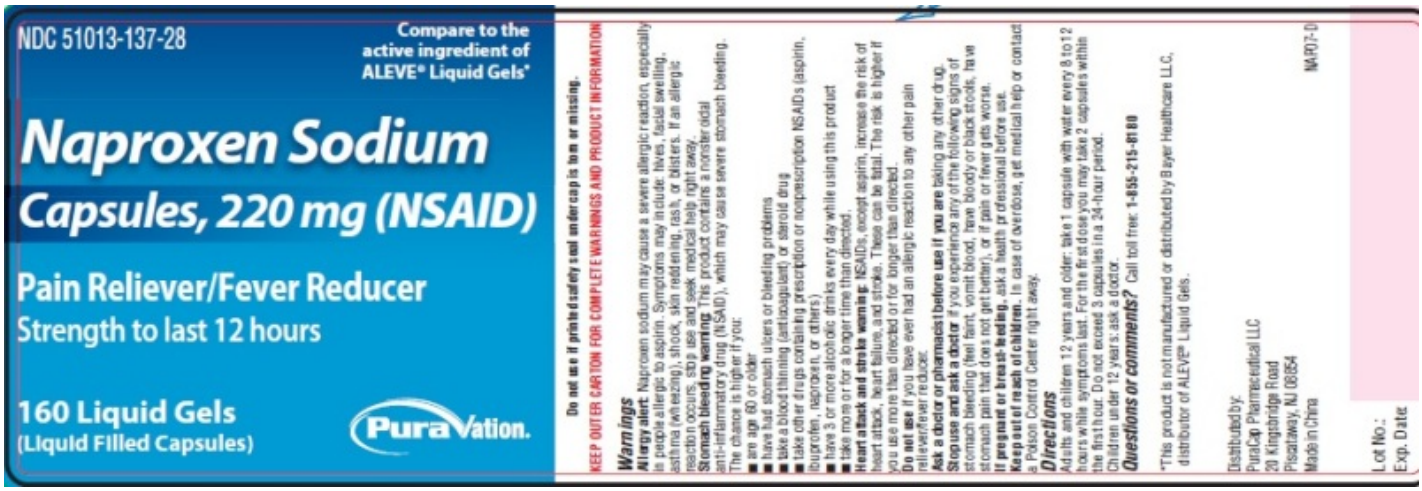
PRINCIPAL DISPLAY PANEL

Naproxen Sodium Capsules, 220 mg (NSAID)

pain reliever/fever reducer

NDC 51013-137-28

160 LIQUID GELS (LIQUID FILLED CAPSULES)



NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-137
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue (CLEAR)	**Score**	no score
Shape	capsule (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	PC19
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51013-137-15	1 in 1 CARTON	03/20/2018	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51013-137-28	1 in 1 CARTON	03/20/2018	
2		160 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51013-137-60	160 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA208363	03/20/2018	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-137) , analysis(51013-137)

Revised: 12/2019 PuraCap Pharmaceutical LLC