RAPIDOL NAPROXEN- naproxen sodium tablet, coated
Pharmadel LLC

Rapidol Naproxen 220mg (HL)

Drug Facts

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Active ingredient & Purposes

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Active ingredient (in each caplet)	***Purposes***
Naproxen sodium 220mg (naproxen 200mg) (NSAID*) *nonsteroidal anti-inflammatory drug	Pain reliver/ 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

Alergy 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 warining: 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, exept 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
- 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:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better

- you have sysmptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - slurred speech
  - leg swelling
  - weakness in one part or side of body

- 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
- 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.

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 of age	• **ask a doctor**

Other information

- **each caplet contains:** sodium 20 mg
- store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- retain carton for complete product information

Inactive ingredients

corn starch, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polythylene glycol, povidone K30, sodium starch glycolate, stearic acid, titanium dioxide, water

Distributed by:

†This product is not manufactured or distributed by Bayer Health LLC., distributor of Aleve. Aleve is a registered mark of bayer Health LLC.

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Prrinicpal Display Panel

55758-048-24

Rapidol Naproxen Sodium 220mg

24 Caplets

RAPIDOL NAPROXEN

naproxen sodium tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-048
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue (Light Blue)	**Score**	score with uneven pieces
Shape	OVAL ((Caplet Shaped))	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-048-24	1 in 1 CARTON	10/09/2019	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55758-048-50	25 in 1 CARTON	10/24/2023	
2	NDC:55758-048-02	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	10/09/2019	

Labeler - Pharmadel LLC (030129680)

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