RAPIDOL NAPROXEN- naproxen sodium tablet, coated
Pharmadel LLC

Rapidol Naproxen 220mg (HHH)

Drug Facts

Drug Facts

Active ingredient and Purposes

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 from arthritis
- menstrual cramps
- muscular aches
- headache
- backache
- toothache
- the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause severe skin reactions. 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drugs

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
- 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
- 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 at 20 weeks or later 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).

Other information

- each caplet contains: **sodium 20 mg**
- store between 68-77°F (20-25°C). Avoid high humidity and excessive heat above 104°F (40°C)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

adults & children 12 years of age 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 of age	• consult a doctor

Inactive ingredients

corn starch, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone k30, sodium starch glycolate, stearic acid, titanium dioxide, water

Distributed by/ Distribuido por:

PHARMADEL LLC

New Castle, DE 19720

Questions? +1-866-359-3478

Made in India/ Hecho en India

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

Prrinicpal Display Panel

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		
3	NDC:55758-048-02	2 in 1 PACKET; Type 0: Not a Combination Product	10/24/2023	

Marketing Information

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

Labeler - Pharmadel LLC (030129680)

Revised: 2/2025 Pharmadel LLC