NAPROXEN SODIUM HEADACHE PAIN CAPLETS- naproxen sodium tablet, coated
NAPROXEN SODIUM BACK AND MUSCLE PAIN CAPLETS- naproxen sodium tablet, coated
Dr.Reddy's Laboratories Inc

NAPROXEN SODIUM
TABLETS USP, 220 mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

Drug Facts

Active ingredient (in each tablet/caplet)

Naproxen sodium USP, 220 mg
(naproxen USP, 200 mg) (NSAID)[1]

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1 nonsteroidal anti-inflammatory drug

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

SPL UNCLASSIFIED SECTION

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.

SPL UNCLASSIFIED SECTION

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you:

are age 60 or olderhave had stomach ulcers or bleeding problems

take a blood thinning (anticoagulant) or steroid drug

take other drugs containing prescription or nonprescription NSAID's (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

SPL UNCLASSIFIED SECTION

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, hear failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

OTC- ASK A DOCTOR SECTION

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

OTC- DO NOT USE SECTION

Do not use

if you have ever had an allergic reaction to any other pain reliever/fever reducer

right before or after heart surgery

OTC - ASK DOCTOR/PHARMACIST SECTION

Ask a doctor or pharmacist before use if you are

under a doctor's care for any serious condition

taking any other drug

OTC - WHEN USING SECTION

When using this product

take with food or milk if stomach upset occurs

OTC - PREGNANCY OR BREAST FEEDING SECTION

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.

OTC - STOP USE SECTION

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

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

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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/caplet every 8 to 12 hours while symptoms last ▪ for the first dose you may take 2 tablets/caplets within the first hour ▪ do not exceed 2 tablets/caplets in any 8 to 12 hour period ▪ do not exceed 3 tablets/caplets in a 24-hour period
Children under 12 years	▪ ask a doctor

Other information

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

Inactive ingredients

FD &C Blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, talc, titanium dioxide

Questions or comments?

call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

Distributed by:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Headache Pain

Headache Pain - Container

Back and Muscle Pain

Back and Muscle Pain- Container

NAPROXEN SODIUM HEADACHE PAIN CAPLETS

naproxen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43598-059
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)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	R;273
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43598-059-52	225 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075168	08/05/2021	

NAPROXEN SODIUM BACK AND MUSCLE PAIN CAPLETS

naproxen sodium tablet, coated

Product Information			
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Ingredient Name	Basis of Strength	Strength
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Labeler - Dr.Reddy's Laboratories Inc (802315887)

Revised: 12/2022 Dr.Reddy's Laboratories Inc