

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

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 older have 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, heart 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 at 20 weeks or later in 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	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 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

Headache Container Label:

Compare to Aleve®
Headache Pain
Caplets active
ingredient**

HEADACHE PAIN

Naproxen Sodium Tablets USP, 220 mg (NSAID)

Pain reliever / fever reducer
STRENGTH TO LAST 12 HOURS
For temporary relief of headache pain
225 Caplets
(Capsule-Shaped Tablets)

TAMPER EVIDENT: Do not use if foil seal under cap printed with "sealed for your protection" is broken or missing.
IMPORTANT: Read the directions and warnings before use.

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium USP, 220 mg
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - menstrual cramps
 - 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
 - asthma (wheezing)
 - skin reddening
 - facial swelling
 - shock
 - rash
 - blisters
- If an allergic reaction occurs, stop use and seek medical help right away.

**This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Aleve®



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Dr. Reddy's Laboratories, Inc.
Princeton, NJ 08540
Made in India

Rev. 05/22

Peel Here 

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LOT
EXP

Drug Facts (continued)

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 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

Drug Facts (continued)

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

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 in 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).

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

- 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).

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

Back and Muscle Pain

Back and Muscle Pain- Container

BACK and MUSCLE PAIN

Naproxen Sodium

Tablets USP, 220 mg (NSAID)

Pain reliever / fever reducer
STRENGTH TO LAST 12 HOURS
For temporary relief of minor back and muscle aches and pains

225 Caplets
(Capsule-Shaped Tablets)

Compare to Aleve® Back and Muscle Pain Caplets active ingredient**

TAMPER EVIDENT: Do not use if foil seal under cap printed with "sealed for your protection" is broken or missing.
IMPORTANT: Read the directions and warnings before use.

Drug Facts

Active ingredient (in each caplet) **Purposes**
Naproxen sodium USP, 220 mg
(naproxen USP, 200 mg) (NSAID) *...Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses
Temporarily relieves minor aches and pains due to:
 ■ backache ■ muscular aches
 ■ minor pain of arthritis ■ 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 ■ blisters
 ■ skin redness ■ rash
 If an allergic reaction occurs, stop use and seek medical help right away.

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Revised: 05/22
 Distributed by:
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 Made in India

Peel Here

LOT 15 00 89 207
 EXP

Drug Facts (continued)

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 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

Drug Facts (continued)

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

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 in 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).

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	■ 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).

Inactive ingredients
 FD & C Blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyoxystalline cellulose, povidone, talc, titanium dioxide

Questions or comments?
 call toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784

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: 3WJQ0SDW1A)	
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-060
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: 3WJQ0SDW1A)	
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:43598-060-52	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	

Labeler - Dr.Reddy's Laboratories Inc (802315887)

Revised: 12/2024

Dr.Reddy's Laboratories Inc