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 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 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	 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

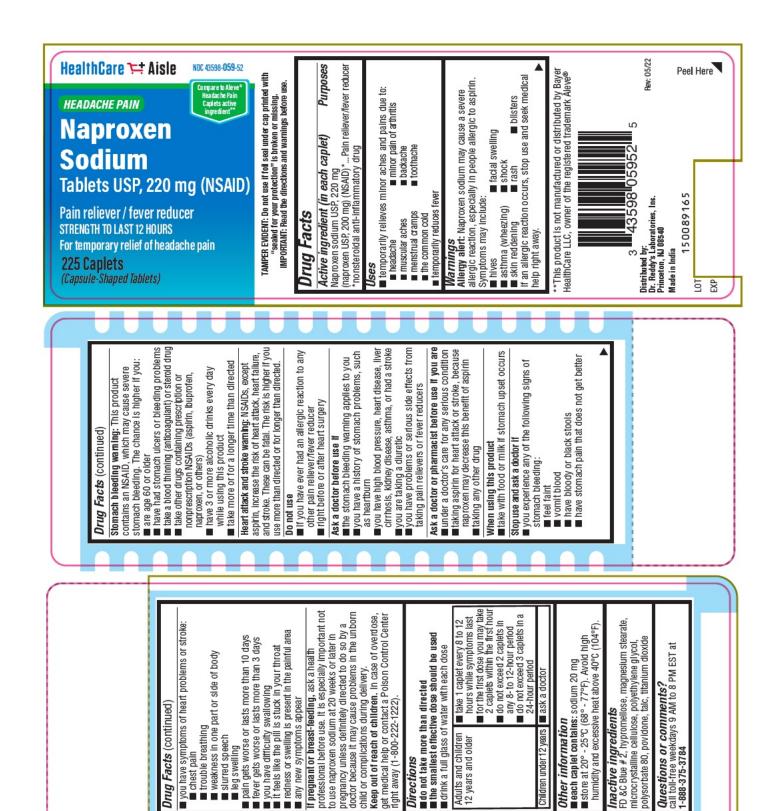
Distributed by:

Dr. Reddy's Laboratories, Inc.

Princeton, NJ 08540

Headache

Headache Container Label:



Directions

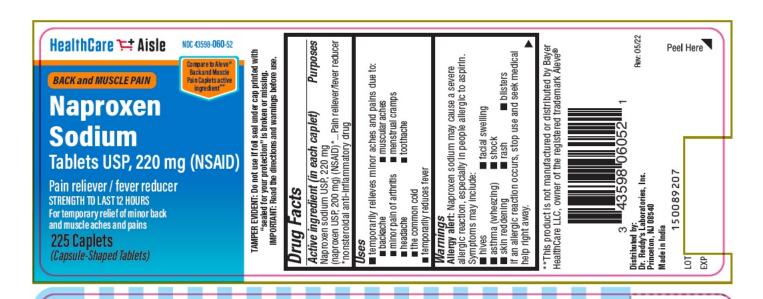
-888-375-3784

Back and Muscle Pain

Back and Muscle Pain- Container

leg swelling

chest pain



Drug Facts (continued

stomach bleeding. The chance is higher if you contains an NSAID, which may cause severe Stomach bloeding warning: This product

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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)

you have symptoms of heart problems or stroke.

Drug Facts (continued

have 3 or more alcoholic drinks every day while using this product

take more or for a longer time than directed

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Do not use

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

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the stomach bleeding warning applies to you ■right before or after heart surgery Ask a doctor before use if

■you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■you have a history of stomach problems, such as heartburn

■you have problems or serious side effects from ■you are taking a diuretic

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

When using this product taking any other drug

■ for the first dose you may take 2 caplets within the first hour

do not exceed 2 caplets in

take 1 caplet every 8 to 12 hours while symptoms last

the smallest effective dose should be used

do not take more than directed

Jirections

drink a full glass of water with each dose

Adults and children

12 years and older

any 8- to 12-hour period
do not exceed 3 caplets in a
24-hour period

■take with food or milk if stomach upset occurs

stomach bleeding feel faint

you experience any of the following signs of

Stop use and ask a doctor li

vomit blood

have stomach pain that does not get better have bloody or black stools

to 8 PM EST at

FD &C Blue # 2, hypromellose, magneslum stearate

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microcrystalline cellulose, polyethylene glycol,

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each caplet contains: sodium 20 mg

Other information

Children under 12 years

Questions or comments toll-free weekdays 9 AM 1-888-375-3784

NAPROXEN SODIUM **HEADACHE PAIN CAPLETS**

you have difficulty swallowing
 If feels like the pill is stuck in your throat
 redness or swelling is present in the painful area

pain gets worse or lasts more than 10 days

weakness in one part or side of body

slurred speech

leg swelling

trouble breathing

chest pain

fever gets worse or lasts more than 3 days

naproxen sodium tablet, coated



Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthNaproxen Sodium (UNII: 9TN87S3A3C) (Naproxen - UNII:57Y76R9ATQ)Naproxen Sodium220 mg

Inactive Ingredients

mactive 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: FZ 989GH94E)				
talc (UNII: 7SEV7J4R1U)				
titanium dioxide (UNII: 15FIX9V2JP)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				

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 Application Number or Monograph Marketing Start Marketing Category Citation Date 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		
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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	
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cellulose, microcrystalline (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
povidone (UNII: FZ989GH94E)		
talc (UNII: 7SEV7J4R1U)		
titanium dioxide (UNII: 15FIX9V2JP)		
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MarketingApplication Number or MonographMarketing StartMarketing EndCategoryCitationDateDate				
ANDA	ANDA075168	08/05/2021		

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

Revised: 12/2024 Dr.Reddy's Laboratories Inc