

NAPROXEN SODIUM- naproxen sodium tablet
NAPROXEN SODIUM- naproxen sodium tablet, film coated
Granules India Ltd

Naproxen Sodium Tablets, USP 220 mg

ACTIVE INGREDIENT(S)

(in each tablet/caplet)

Naproxen sodium 220 mg (Naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

- 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

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.

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 had 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

- under a doctor's care for any serious condition
- taking any other drug

WHEN USING THIS PRODUCT

- take with food or milk if stomach upset occurs

STOP USE AND ASK 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

PREGNANCY/BREASTFEEDING

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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • ask a doctor |

OTHER INFORMATION

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

INACTIVE INGREDIENT

Inactive Ingredients FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments?

1-877-770-3183 Mon - Fri 9:00 AM to 4:30 PM EST

Do not use if carton is open or if foil seal on bottle opening is missing or broken.

Manufactured By:
Granules India Limited
 Hyderabad -500 081, India
MADE IN INDIA
 M.L. 37/RR/AP/2003/F/R

PRINCIPAL DISPLAY PANEL

NDC 62207-327-49
Compare to the Active
Ingredient of Aleve® Tablets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**

HEADACHE PAIN

Pain reliever/fever reducer

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

1000 Tablets

for temporary relief
of headache pain

DO NOT USE IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN.

Drug Facts

Active ingredient
(In each caplet)
Naproxen sodium 220 mg
(Naproxen 200 mg) (NSAID)**
*nonsteroidal anti-inflammatory drug

Purposes
Pain reliever/fever reducer

Uses
temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ muscle aches ■ backache ■ menstrual cramps ■ headache ■ toothache ■ a common cold ■ temporarily reduces fever

Warnings
Always 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 redness/itch ■ 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 recent or long-term use of drugs that may increase the risk of bleeding (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 ■ light bulbs or after heart surgery

Ask a doctor before use if
■ you have a history of stomach problems such as heartburn ■ you have had 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

This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is a registered trademark of Bayer HealthCare, LLC.

Manufactured By:

Granules India Limited
 Hyderabad-500081, INDIA
MADE IN INDIA

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 FEEL HERE

Drug Facts (continued)

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 ■ see signs of heart problems or other chest pain ■ have a sudden change in vision ■ have a sudden change in hearing ■ have a sudden change in speech ■ get swelling ■ skin gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ you have difficulty swallowing ■ 1 week the pain is back to your throat ■ redness or swelling is present in the painful area ■ any new symptoms appear

Preparation: If available, use a white prescription bottle. Use it especially if product not to use naproxen sodium requires a prescription. Preparation of capsules contains crushed tablets so by a doctor because it may cause problems in the intestine or on operation

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (911 area).

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 ■ or 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 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-877-770-3183 Mon - Fri 9:00 AM to 4:30 PM EST

NDC 62207-327-51
Compare to the Active
Ingredient of Aleve® Tablets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**

HEADACHE PAIN

Pain reliever/fever reducer

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

10 Tablets for temporary relief of headache pain

**DO NOT USE IF FOIL SEAL ON BOTTLE
OPENING IS MISSING OR BROKEN.**

Drug Facts

Active Ingredient (in each tablet)
Naproxen sodium 220 mg.....Pain reliever/fever reducer (NSAID)** - fever reducer nonsteroidal anti-inflammatory drug

Purposes
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

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
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.
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 thinner (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen,

RETAIN CARTON FOR COMPLETE
DRUG FACTS LABELING INFORMATION
Manufactured By:
Granules India Limited
Hyderabad - 500 081, INDIA
MADE IN INDIA

(CONTINUED ON BACK OF LABEL)

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Drug Facts (continued)
naproxen, or other) ■ have 3 or more alcohol drinks every day while using the 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 had 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 its 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: ■ heart burn ■ 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 ■ sudden speech ■ leg swelling ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ it takes for the pill to stick 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

Drug Facts (continued)

important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to 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

Adults and children 12 years and older
■ drink a full glass of water with each dose ■ take 1 or 2 tablets every 8 to 12 hours, with or without food, as needed ■ take 1 or 2 tablets with the first hour ■ do not take more than 2 tablets in any 8-hour period ■ do not take more than 3 tablets in a 24-hour period

Children under 12 years
■ ask a doctor

Other information
■ each tablet 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 FDAC blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone K-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments?
1-877-770-3183
Mon - Fri 9:00 AM to 4:00 PM EST

*This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is registered trademark of Bayer HealthCare, LLC.

NDC 62207-328-49
Compare to the Active
Ingredient of Aleve® Caplets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**

HEADACHE PAIN

Pain reliever/fever reducer

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

1000 Caplets†
(†Capsule-Shaped Tablets)



for temporary relief
of headache pain

DO NOT USE IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN.

Drug Facts

Active Ingredient (in each caplet)

Naproxen sodium 220 mg _____ Pain reliever/fever reducer
(naproxen 220 mg (NSAID)**)

*nonsteroidal anti-inflammatory drug

Uses

temporarily relieve minor aches and pains due to: ■ minor pain of arthritis ■ muscular aches ■ backache ■ menstrual cramps ■ headache ■ toothache ■ the common cold ■ temporarily reduce 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 ■ skin redness ■ 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 ever had stomach ulcers or bleeding ■ are taking aspirin, aspirin/acetaminophen, or other NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ take 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.

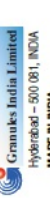
Do not use: ■ If you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

Ask a doctor before you use if: ■ you have a history of stomach problems ■ 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: ■ taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin ■ taking any other drug

This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is registered trademark of Bayer HealthCare, LLC.

Manufactured by:



Gramules India Limited
Hyderabad - 500 081, INDIA

MADE IN INDIA



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DO NOT USE IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN.

Drug Facts (continued)

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: ■ belching

■ 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 ■ teeth like the pit 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 clearly 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

■ take 1 caplet every 8 to 12 hours while symptoms last

■ or 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

■ 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

(106°F).

Inactive ingredients: FD&C Blue2, aluminum oleate, hydrocodone 291.0, maize starch,

microcrystalline cellulose, polyethylene glycol, polydioxanone K-30, sodium starch glycolate,

silicic acid, titanium dioxide

Questions or Comments? 1-877-735-1818 Mon-Fri 9:00 AM to 4:00 PM EST

NDC 62207-328-51
Compare to the Active
Ingredient of Aleve® Caplets*

Naproxen Sodium Tablets USP

220 mg (HISAID)**

HEADACHE PAIN

Pain reliever/fever reducer
Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

10 Caplets*
(*Capsule-Shaped Tablets)

for temporary relief
of headache pain

**DO NOT USE IF FOL SEAL ON BOTTLE
OPENING IS MISSING OR BROKEN.**

Drug Facts

Active Ingredient (In each caplet)
Naproxen sodium 220 mg.....Pain reliever/
(naproxen 200 mg) (NSAID)** fever reducer
**nonsteroidal anti-inflammatory drug

Purposes
■ 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

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
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 redness ■ 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).

(CONTINUED ON BACK OF LABEL)

RETAIN CARTON FOR COMPLETE
DRUG FACTS LABELING INFORMATION

Manufactured By:
Granules India Limited
Hyderabad - 500 081, INDIA
MADE IN INDIA.

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Coating Free

Drug Facts (continued)
naproxen or aspirin) ■ have 3 or more
alcoholic drinks each 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 risks are 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
had 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
disease ■ 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: ■ black stools
■ blood ■ dark stools ■ vomit
■ have stomach pain that does not get better
■ you have symptoms of heart problems or
stroke: ■ chest pain ■ shortness of breath
■ 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 parotid
area ■ any new symptoms appear
If pregnant or breast-feeding, ask a
health professional before use. It is especially

Drug Facts (continued)

Important: Do not use naproxen sodium during
the last 3 months of pregnancy unless directed
by your doctor because it may
cause 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 or 2 caplets every 8 to 12 hours as
needed. Do not take more than 3 caplets in
a 24-hour period.

**Children
under 12
years**
■ ask a doctor
■ each caplet contains sodium 20 mg
■ store at 20° - 25°C (68° - 77°F). Avoid high
humidity and excessive heat (not above 40°C
(104°F)).

In active ingredients: F3M C buel2
aluminum lake, hydroxymethylcellulose 2310,
maize starch, microcrystalline cellulose,
polyethylene glycol, povidone K-30, sodium
starch glycolate, stearic acid, titanium dioxide

Questions or Comments?
1-877-770-3183
Mon - Fri 8:00 AM to 4:00 PM EST
*This product is not manufactured or
distributed by Bayer HealthCare, LLC,
distributor of Aleve. Aleve is registered
Trademark of Bayer HealthCare, LLC.

NDC 62207-762-49
Compare to the Active
Ingredient of Aleve® Caplets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**

Pain reliever/fever reducer

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS



1000 Caplets!
(1 Capsule-Shaped Tablet)

DO NOT USE IF FOIL SEAL ON BOTTLE TOPPING IS MISSING OR BROKEN.

Drug Facts

Active Ingredient
(In each caplet)

Naproxen sodium 220 mg (NSAID)**
(Naproxen 200 mg) (NSAID)**
*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer
 ■ minor pain of arthritis
 ■ rheumatoid arthritis
 ■ osteoarthritis
 ■ menstrual cramps
 ■ headache
 ■ toothache
 ■ temporary reduction of fever

Uses

Warnings
 Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in children. Stop use of this product if you experience hives, itching, or rash. If an allergic reaction occurs, stop use and seek medical help right away.
 ■ stomach, heartburn, or indigestion
 ■ dizziness
 ■ fainting or lightheadedness
 ■ sudden weight gain
 ■ swelling of the hands or feet
 ■ difficulty breathing

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 thinner (anticoagulant) or steroid drug ■ take other drugs containing aspirin 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.

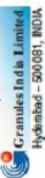
Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery

Ask your doctor before you use:
 ■ if you are pregnant or breastfeeding
 ■ if you have a history of stomach problems, such as heartburn ■ if you have had high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■ if you are taking a diuretic
 ■ if you have problems or serious side effects from taking pain relievers or fever reducers

Ask your doctor or pharmacist before use if you are:
 ■ under a doctor's care for any serious condition ■ taking any other drug

*This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is a registered trademark of Bayer HealthCare, LLC.

Manufactured By:



MADE IN INDIA



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Drug Facts (continued)

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: ■ low hemoglobin ■ 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 of body ■ slurred speech
- leg swelling ■ pain, gas, or cramps more than 10 days ■ water, gas, or stool more than 3 days ■ you're having difficulty swallowing ■ blood in the stool ■ your mouth ■ redness or swelling of feet or in the genital 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 explicitly 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 is 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° to 25° (68° to 77°). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive Ingredients: DMC Blue2 aluminum silicate, hydroxyethylcellulose, microcrystalline cellulose, polyethylene glycol, povidone-K30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-877-776-8333 Mon - Fri 9:00 AM to 4:00 PM EST

NDC 62207-761-49
Compare to the Active
Ingredient of Aleve® Tablets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**

Pain reliever/fever reducer

Contains no ingredient made from a
gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

1000 Tablets



DO NOT USE IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN

Drug Facts

Active ingredient
(in each tablet)

Naproxen sodium 220 mg
(Equivalent to 200 mg of naproxen)**

*The combination of
naproxen sodium and aspirin is

Purposes

- Pain reliever/fever reducer
- Temporary relief of arthritis symptoms, including osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis
- Temporary relief of menstrual pain

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people with asthma. Symptoms may include: hives; facial swelling; difficulty breathing; wheezing; or difficulty swallowing. Do not use naproxen sodium if you are allergic to aspirin or other NSAIDs.

Should be used with caution: Naproxen sodium may increase your risk of heart disease, stroke, and high blood pressure. Use with caution if you have heart disease, stroke, high blood pressure, or if you are taking medication to treat these conditions. Tell your doctor if you have any of these conditions.

Heart alert 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 take more than directed unless your doctor tells you to. Do not take more than directed if you have any of the following conditions: heart failure, kidney disease, liver disease, or if you are taking a diuretic, a blood thinner, or a medicine for high blood pressure.

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for a stomach condition
- taking any other drug

Other information

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

Inactive ingredients: FD&C blue 2 aluminum lake, hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol, polyethylene glycol, sodium starch glycolate, dibutyltin dilaurate, titanium dioxide

Questions or Comments? 1-877-776-3183 Mon - Fri 9:00 AM to 4:00 PM EST



Made in India

Crosses India Limited
Hyderabad - 500 061, INDIA

Manufactured by:
Bayer HealthCare, LLC,
 distributor of Aleve, Naproxen Sodium Tablets, of Bayer HealthCare, LLC.

Lot #
EXP



Drug Facts (continued)

When using this product: Use with food or milk if stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the warning signs of stomach bleeding: see below
- you notice black, bloody, or tarry stools; or see or notice red or bloody urine
- you see or notice red or bloody stools; or see or notice red or bloody urine
- you notice vomiting of blood or material that looks like coffee grounds
- you notice black, bloody, or tarry stools; or see or notice red or bloody urine
- you notice vomiting of blood or material that looks like coffee grounds
- you notice black, bloody, or tarry stools; or see or notice red or bloody urine

Directions

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

Adults and children 12 years and older:

- take 1 tablet every 8 to 12 hours while symptoms last
- do not exceed 3 tablets in any 24-hour period

Children under 12 years:

- ask a doctor

Other information:

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

Inactive ingredients: FD&C blue 2 aluminum lake, hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol, polyethylene glycol, sodium starch glycolate, dibutyltin dilaurate, titanium dioxide

Questions or Comments? 1-877-776-3183 Mon - Fri 9:00 AM to 4:00 PM EST

NDC 62207-728-49
Compare to the Active Ingredient of Aleve® Tablets*

Naproxen Sodium Tablets USP

220 mg (NSAID)**
Pain reliever/fever reducer

BACK & MUSCLE PAIN

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

STRENGTH TO LAST 12 HOURS

1000 Tablets

DO NOT USE IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN

| Active Ingredient (in each tablet) | Purposes |
|---|-----------------------------|
| Naproxen sodium 220 mg (NSAID)** nonparacetamol/acetaminophen free | 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

Alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma
- hoarseness
- skin rash
- skin redness
- itching
- blistering
- an allergic reaction occurs.

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 aspirin drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, etc.)
- take any of these drugs every day
- take this product for a longer time than directed

Heart attack and stroke warning (NSAIDs): Except aspirin, because 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 or 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 had high blood pressure, heart disease, liver problems, 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 or taking any other drug

This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is a registered trademark of Bayer HealthCare, LLC.

Manufactured By:
Granules India Limited
Hyderabad - 500081, INDIA
MADE IN INDIA

62207172849112

LOT
EXP
Cooling Free

Drug Facts (continued)

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:
 - weak or vomit blood
 - black stools
 - black or tarry stools
 - stomach pain that does not get better
 - you have symptoms of heart problems or stroke
 - chest pain
 - trouble breathing
 - swelling in your feet or ankles
 - stomach or belly bloating
 - stomach or belly pain
 - stomach or belly pain that is worse than 3 days
 - you have difficulty swallowing
 - stomach or belly pain that is worse than 3 days
 - you have difficulty swallowing
 - stomach or belly pain that is worse than 3 days
 - you have difficulty swallowing
 - stomach or belly pain that is worse than 3 days
 - any new symptoms appear

If pregnant or breast-feeding, ask health care provider before use. This especially applies to those taking naproxen sodium during the last 3 months of pregnancy, unless expressly 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
- See warnings: effects a dose should be used
- drink a full glass of water with each dose

| Adults and children 12 years and older | Children under 12 years |
|--|--|
| <ul style="list-style-type: none"> Take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets with the first dose. Do not exceed 2 tablets every 6 to 8 hours period. Do not exceed 3 tablets in a 24-hour period. | <ul style="list-style-type: none"> Ask a doctor |

Other information

- each tablet contains sodium 20 mg
- store at 20° - 25° (68° - 77°), avoid humidity and excessive heat above 40°C (104°F)

See the important information about naproxen sodium tablets on the inside of the bottle.

Questions or Comments? 1-877-728-1831 Mon - Fri 9:00 AM to 4:00 PM EST

| NAPROXEN SODIUM | | | |
|---|-------------------|--------------------|---------------|
| naproxen sodium tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-328 |
| 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) | | | |
| STARCH, CORN (UNII: O8232NY35J) | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | |
| POVIDONE K30 (UNII: U725QWY32X) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |

| Product Characteristics | | | | |
|-------------------------|--|---|----------------------|--------------------|
| Color | blue (Light Blue) | Score | no score | |
| Shape | ROUND | Size | 10mm | |
| Flavor | | Imprint Code | 220 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62207-328-41 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 2 | NDC:62207-328-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 3 | NDC:62207-328-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 4 | NDC:62207-328-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 5 | NDC:62207-328-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA091353 | 07/16/2021 | | |

| NAPROXEN SODIUM | | | |
|---|-------------------|---------------------------|---------------|
| naproxen sodium tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-327 |
| 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) | | | |
| STARCH, CORN (UNII: O8232NY35J) | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | |
| POVIDONE K30 (UNII: U725QWY32X) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| STEARIC ACID (UNII: 4ELV7Z 65AP) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |
| Product Characteristics | | | |
| Color | blue (Light Blue) | Score | no score |

| Shape | OVAL (Caplet -Shaped) | Size | 12mm | |
|------------------------------|--|---|----------------------|--------------------|
| Flavor | | Imprint Code | 220 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62207-327-41 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 2 | NDC:62207-327-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 3 | NDC:62207-327-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 4 | NDC:62207-327-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| 5 | NDC:62207-327-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 07/16/2021 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA091353 | 07/16/2021 | | |

NAPROXEN SODIUM

naproxen sodium tablet, film coated

| Product Information | | | |
|---|-------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-761 |
| 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) | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | |
| POVIDONE K30 (UNII: U725QWY32X) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| STEARIC ACID (UNII: 4ELV7Z 65AP) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |
| Product Characteristics | | | |
| Color | blue (Light Blue) | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | 220 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62207-761-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| 2 | NDC:62207-761-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| 3 | NDC:62207-761-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| 4 | NDC:62207-761-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA091353 | 09/30/2011 | |

| NAPROXEN SODIUM | | | | |
|-------------------------------------|---|--|----------------------|--------------------|
| naproxen sodium tablet, film coated | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-762 | |
| 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) | | | |
| | STARCH, CORN (UNII: O8232NY35J) | | | |
| | CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| | POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | | |
| | POVIDONE K30 (UNII: U725QWY32X) | | | |
| | SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| | STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| | TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |
| Product Characteristics | | | | |
| Color | blue (Light Blue) | Score | no score | |
| Shape | OVAL (Caplet -Shaped) | Size | 12mm | |
| Flavor | | Imprint Code | 220 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:62207-762-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| | NDC:62207-762-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|---|------------|--|
| 2 | NDC:62207-762-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| 3 | NDC:62207-762-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |
| 4 | NDC:62207-762-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 09/30/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091353 | 09/30/2011 | |

NAPROXEN SODIUM

naproxen sodium tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-728 |
| 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) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|-------------------|--------------|----------|
| Color | blue (Light Blue) | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 220 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62207-728-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 2 | NDC:62207-728-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 3 | NDC:62207-728-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 4 | NDC:62207-728-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 5 | NDC:62207-728-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091353 | 06/08/2018 | |

NAPROXEN SODIUM

naproxen sodium tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62207-729 |
| 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) | |
| STARCH, CORN (UNII: O8232NY3S) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|-----------------------|--------------|----------|
| Color | blue (Light Blue) | Score | no score |
| Shape | OVAL (Caplet -Shaped) | Size | 12mm |
| Flavor | | Imprint Code | 220 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62207-729-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 2 | NDC:62207-729-42 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 3 | NDC:62207-729-43 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 4 | NDC:62207-729-47 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |
| 5 | NDC:62207-729-49 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 06/08/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091353 | 06/08/2018 | |

Labeler - Granules India Ltd (915000087)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---|
| Granules India Ltd | | 918609236 | manufacture(62207-728, 62207-729, 62207-761, 62207-762, 62207-327, 62207-328) |

Revised: 2/2023

Granules India Ltd