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	• 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	• 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

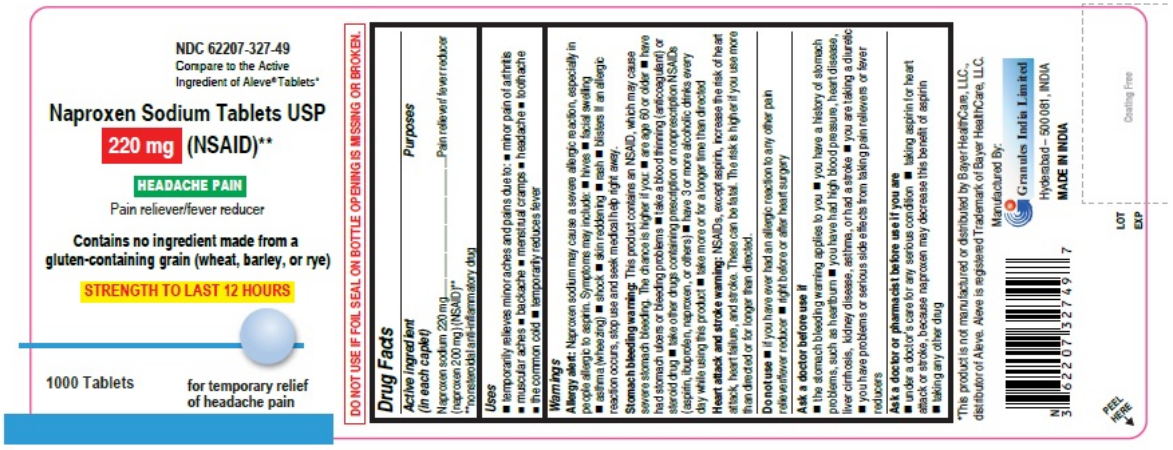
Inactive Ingredients FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

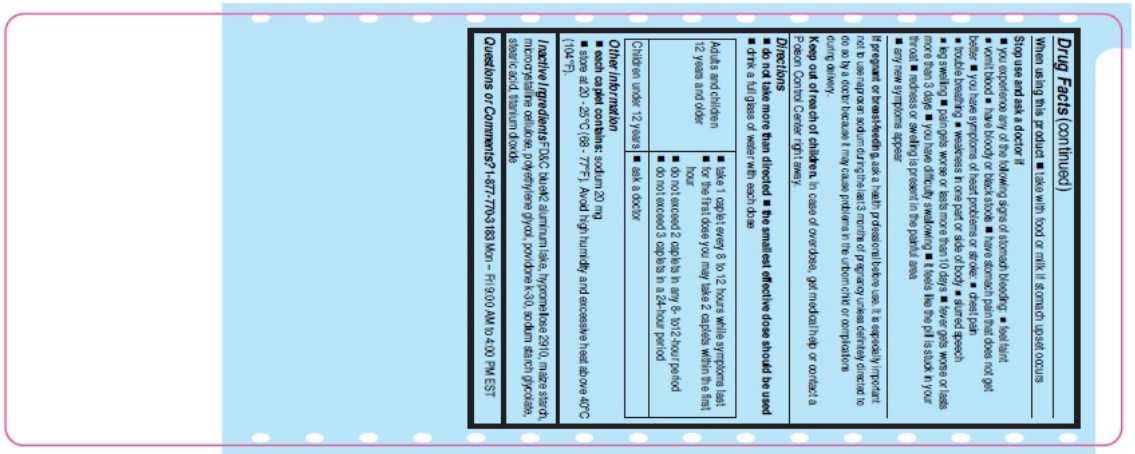
Questions or Comments?
1-877-770-3183 Mon - Fri 9:00 AM to 4:30 PM EST

Do not use if carton is open or of 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 62207-327-51

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)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)**	Pain reliever/ fever reducer

**nonsteroidal anti-inflammatory drug

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 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

PEEL HERE

LOT

EXP

Coating Free

Drug Facts (continued)

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 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 ■ 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 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	■ 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- to12-hour period ■ do not exceed 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 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 4:00 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)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)** **nonsteroidal anti-inflammatory drug	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

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 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

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

LOT
EXP

Coating Free
Coating Free

PEEL 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
- 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 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.

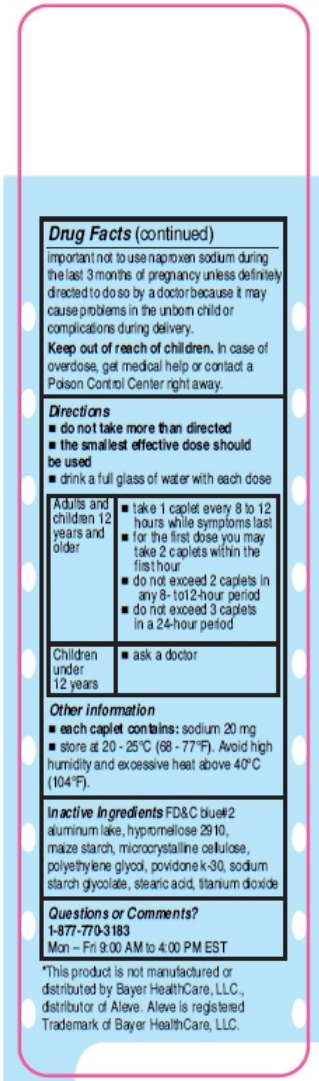
Directions
- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

Adults and children 12 years and older	■ 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 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-877-795-1858 Mon – Fri 9:00 AM to 4:00 PM EST



Drug Facts (continued)

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**
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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 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

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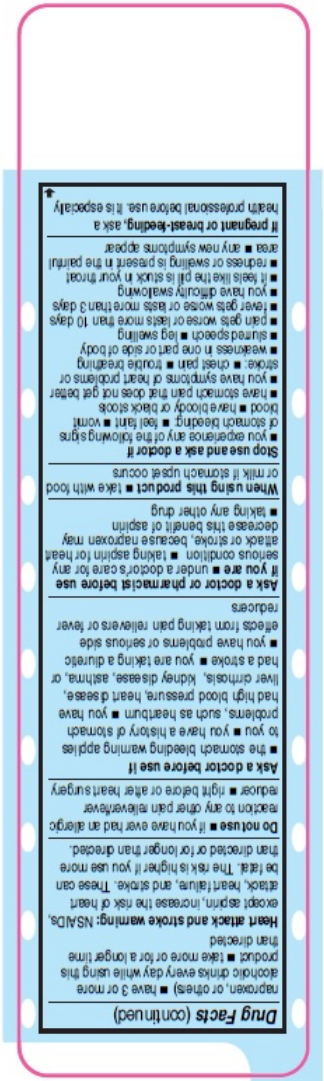


Drug Facts (continued)

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

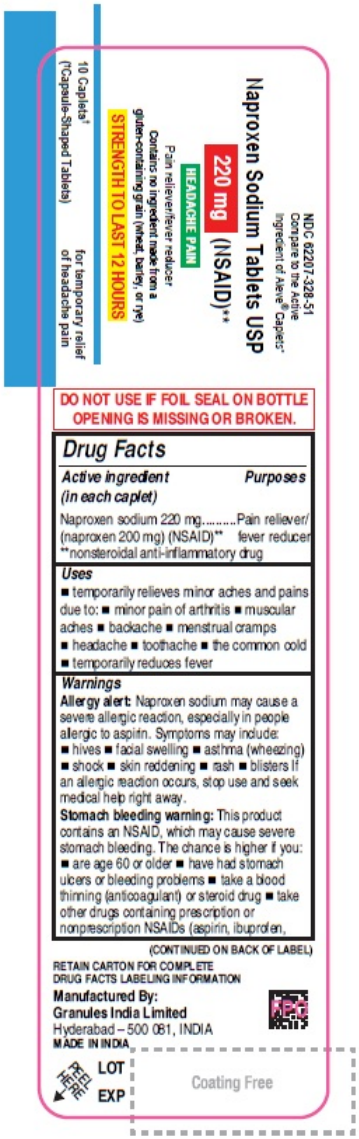
Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin ■ taking any other drug

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 ■ 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



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†
(†Capsule-Shaped Tablets)

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

Drug Facts

Active ingredient (in each caplet)	*Purposes*
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)**	Pain reliever/ fever reducer

**nonsteroidal anti-inflammatory drug

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 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 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 registered Trademark of Bayer HealthCare, LLC.

Manufactured By:
Granules India Limited
Hyderabad – 500 081, INDIA

MADE IN INDIA

LOT
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Coating 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: ■ 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 food 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 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	■ 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 8-10-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 k-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-877-762-7183 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)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)**	Pain reliever/fever reducer

**nonsteroidal anti-inflammatory drug

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 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 you are ■ under a doctor's care for any serious condition ■ taking any other drug

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Manufactured By

Granules India Limited

Hyderabad – 500 081, INDIA

MADE IN INDIA

LOT

EXP

Coating Free

PEEL 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 ■ you have sympt0m or 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 ■ hoarseness 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 cause problems 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 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	■ 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 FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

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NDC 62207-729-49
Compare to the Active Ingredient of Aleve®Caplets*

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 Caplets†
(†Capsule-Shaped Tablets)

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

Drug Facts

Active ingredient (in each caplet)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)**	Pain reliever/ fever reducer

**nonsteroidal anti-inflammatory drug

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

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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 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 registered Trademark of Bayer HealthCare, LLC.

Manufactured By:
Granules India Limited
Hyderabad – 500 081, INDIA

MADE IN INDIA

LOT
EXP

Coating 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 ■ 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 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 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

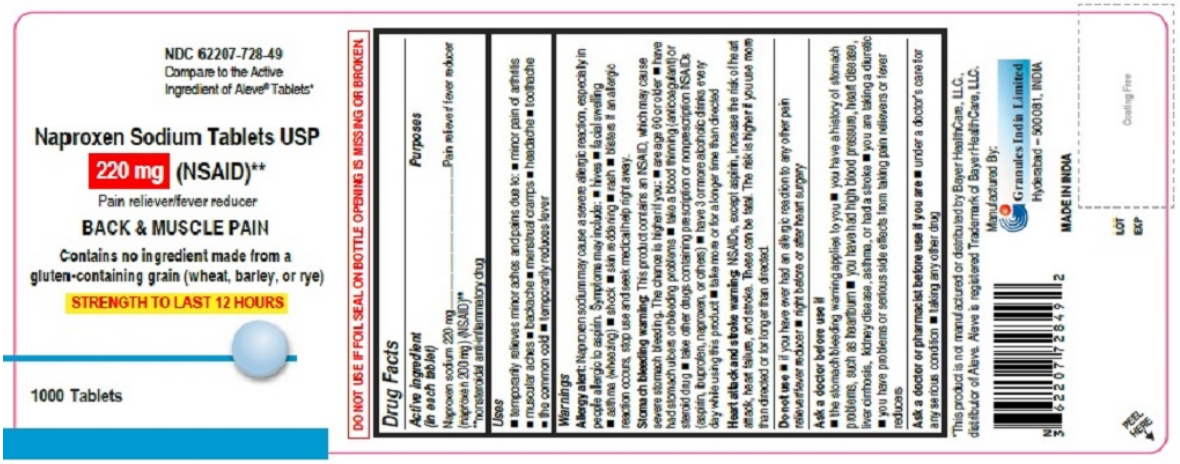
Adults and children 12 years and older	■ take 1 caplet every 8 to 12 hours while symptoms last ■ for the first dose you may take 2 caplets within the first hour ■ do not exceed 2 caplets in any 8- to 12-hour period ■ do not exceed 3 caplets in a 24-hour period
Children under 12 years	■ ask a doctor

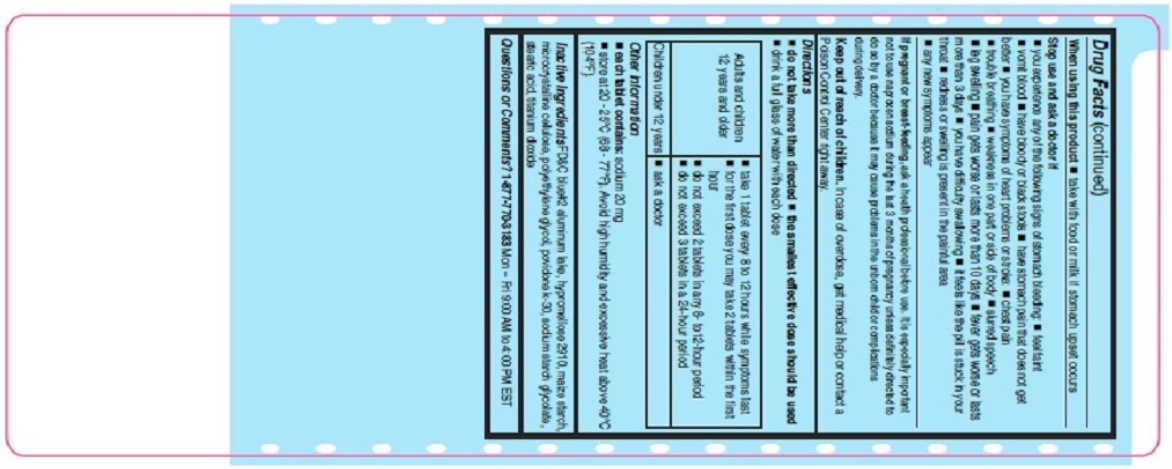
Other information

■ **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 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-90, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-877-770-9183 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: 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:62207-328-41	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: 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	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: 4ELV7Z65AP)	
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: 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	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	

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: 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	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