NAPROXEN SODIUM- naproxen sodium tablet
Granules India Limited

Naproxen Sodium Tablets

ACTIVE INGREDIENT

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

INDICATIONS AND USAGE

- 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

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 DOCTOR
- 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, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

ASK DOCTOR/PHARMACIST
- under a doctor’s care for any serious condition
- taking any other drug

WHEN USING
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

STOP USE
- 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
- 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
- you develop heartburn
- redness or swelling is present in the painful area
- any new symptoms appear

PREGNANCY 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.

DOSAGE AND ADMINISTRATION

- **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

Information for Patients

- **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)
- do not use if foil seal on bottle opening is missing or broken.

INACTIVE INGREDIENT

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

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

M.L. 37/RR/AP/2003/F/R

MADE IN INDIA

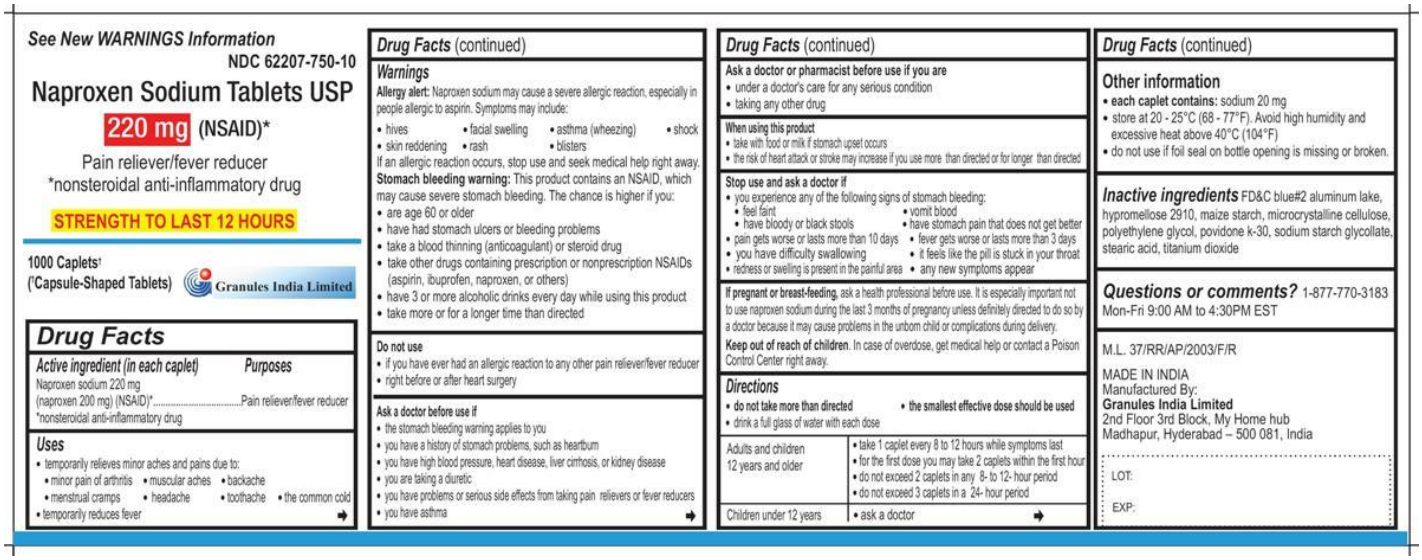
Manufactured By:

Granules India Limited

2nd Floor 3rd Block, My Home hub

Madhapur, Hyderabad – 500 081, India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



See New WARNINGS Information

NDC 62207-750-10

Naproxen Sodium Tablets USP

220 mg (NSAID)*

Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

STRENGTH TO LAST 12 HOURS

1000 Caplets†

(†Capsule-Shaped Tablets)

Granules India Limited

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

Drug Facts (continued)

Warnings

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- shock
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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)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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

Drug Facts (continued)

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)
- do not use if foil seal on bottle opening is missing or broken.

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

Questions or comments? 1-877-770-3183

Mon-Fri 9:00 AM to 4:30PM EST

M.L. 37/RR/AP/2003/F/R

MADE IN INDIA

Manufactured By:

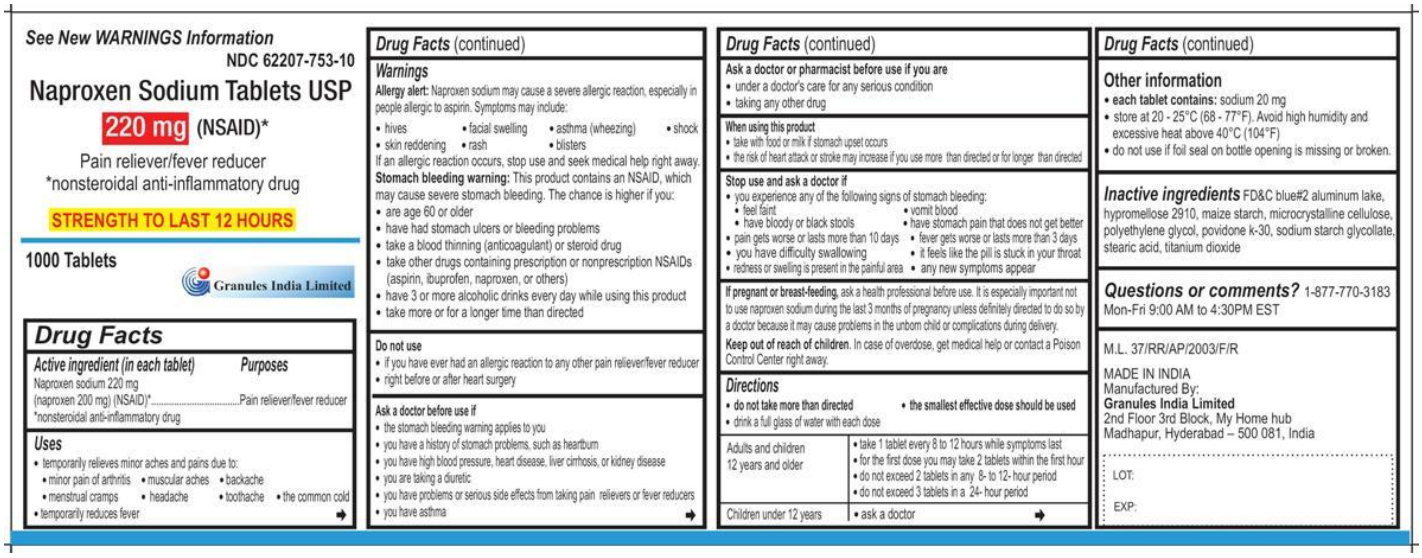
Granules India Limited

2nd Floor 3rd Block, My Home hub

Madhapur, Hyderabad – 500 081, India

LOT:

EXP:



See New WARNINGS Information

NDC 62207-753-10

Naproxen Sodium Tablets USP

220 mg (NSAID)*

Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

STRENGTH TO LAST 12 HOURS

1000 Tablets

Granules India Limited

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

Drug Facts (continued)

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

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- 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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

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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

Drug Facts (continued)

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

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MADE IN INDIA

Manufactured By:

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2nd Floor 3rd Block, My Home hub

Madhapur, Hyderabad – 500 081, India

LOT:

EXP:

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62207-750
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	I1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-750-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
2	NDC:62207-750-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
3	NDC:62207-750-43	43 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
4	NDC:62207-750-44	150 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
5	NDC:62207-750-45	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
6	NDC:62207-750-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
7	NDC:62207-750-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
8	NDC:62207-750-51	10 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
9	NDC:62207-750-52	300 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
10	NDC:62207-750-53	400 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:62207-753
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-753-41	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
2	NDC:62207-753-42	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
3	NDC:62207-753-43	43 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
4	NDC:62207-753-44	150 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2011	
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Marketing Information

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

Labeler - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	analysis(62207-750, 62207-753) , manufacture(62207-750, 62207-753) , pack(62207-750, 62207-753) , label(62207-750, 62207-753)

Revised: 12/2023 Granules India Limited