

NAPROXEN SODIUM - naproxen sodium tablet, film coated
Aurohealth LLC

Naproxen Sodium Tablets, USP 220 mg

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium USP 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
- muscular aches
- menstrual cramps
- toothache
- backache
- headache
- 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 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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 | ask a doctor |

Other information

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

Inactive ingredients

colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, and titanium dioxide

Questions or comments?

1-855-274-4122

Distributed by: **AUROHEALTH LLC**
279 Princeton-Hightstown Road,
East Windsor, NJ 08520
Made in India

Code: TS/DRUGS/22/2009

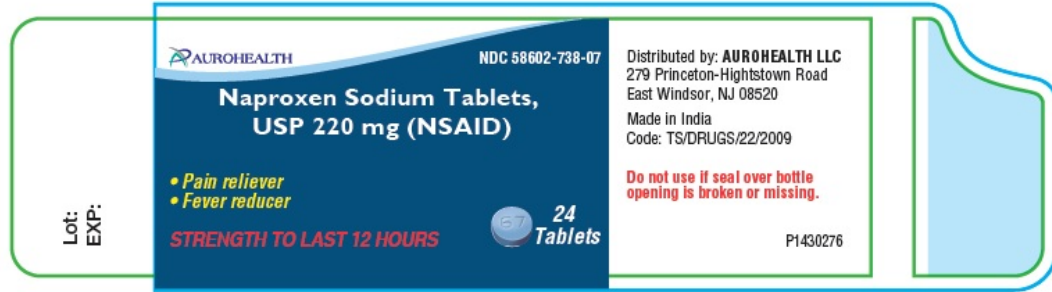
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (24 Tablets, Container Label)

AUROHEALTH
NDC 58602-738-07
Naproxen Sodium Tablets,
USP 220 mg (NSAID)

- ***Pain reliever***
- ***fever reducer***

STRENGTH TO LAST 12 HOURS
24 Tablets

Base



Booklet Placement

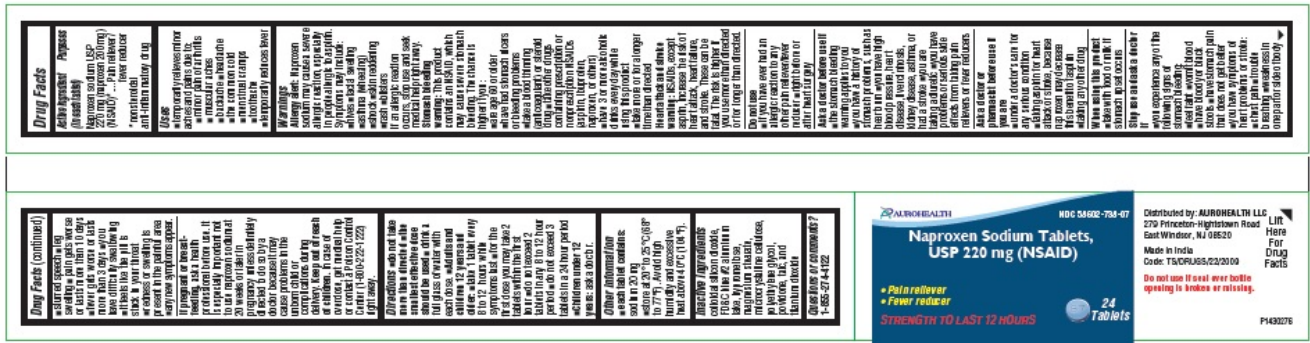
Booklet

Page #2
(Back of Cover)

Page #3

Page #4

Back



Front

Page #5

Page #6

Cover
(Page #1)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (24 Tablets Carton Label)

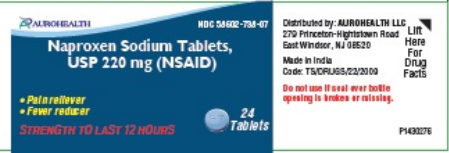
AUROHEALTH
NDC 58602-738-07

****Compare to Aleve®**

active ingredient
Naproxen Sodium Tablets, USP
220 mg (NSAID)

- Pain reliever
- fever reducer

STRENGTH TO LAST 12 HOURS
24 Tablets



Distributed by: AUROHEALTH LLC
 279 Princeton-Hightstown Road
 East Windsor, NJ 08520
 Made in India
 Code: TS/DRUGS/2/2/2009

**This product is not Manufactured or distributed by Bayer Healthcare LLC, distributor of Aleve®
 Do not use if carton is open or if seal over bottle opening is broken or missing.



Unvarnish Zone (dotted line for perforation)

Drug Facts (continued)

- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

| | |
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| 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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

NDC 58602-738-07
 **Compare to Aleve® active ingredient

Naproxen Sodium Tablets, USP
220 mg (NSAID)

24 Tablets

STRONG BY DAY LAST 12 HOURS

AUROHEALTH

- Pain reliever
- Fever reducer

Drug Facts

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

Uses

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Drug Facts (continued)

If you use more than directed or for longer than directed.

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- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech

Drug Facts (continued)

Inactive ingredients coloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, talc, and titanium dioxide

Questions or comments? 1-855-274-4122

P1047943

Lot:
EXP:

Unvarnish Zone (dotted line not for perforation)

Unvarnish Zone (dotted line for perforation)

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-738 |
| 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 |
|------------------------------------|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

| | |
|---|--|
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | BLUE (light blue) | Score | no score |
| Shape | ROUND (Circular) | Size | 10mm |
| Flavor | | Imprint Code | J;67 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----|------------------|--|----------------------|--------------------|
| 1 | NDC:58602-738-07 | 1 in 1 CARTON | 03/18/2016 | |
| 1 | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:58602-738-12 | 1 in 1 CARTON | 03/18/2016 | |
| 2 | | 40 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:58602-738-14 | 1 in 1 CARTON | 03/18/2016 | |
| 3 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:58602-738-21 | 1 in 1 CARTON | 03/18/2016 | |
| 4 | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 5 | NDC:58602-738-25 | 1 in 1 CARTON | 03/18/2016 | |
| 5 | | 130 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 6 | NDC:58602-738-29 | 1 in 1 CARTON | 03/18/2016 | |
| 6 | | 150 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 7 | NDC:58602-738-34 | 1 in 1 CARTON | 03/18/2016 | |
| 7 | | 200 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 8 | NDC:58602-738-38 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 03/18/2016 | |
| 9 | NDC:58602-738-40 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 03/18/2016 | |
| 10 | NDC:58602-738-44 | 400 in 1 BOTTLE; Type 0: Not a Combination Product | 03/18/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA205497 | 03/18/2016 | |

Labeler - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(58602-738) , MANUFACTURE(58602-738) |

Revised: 12/2023

Aurohealth LLC