

**NAPROXEN SODIUM HEADACHE PAIN - naproxen sodium tablet, film coated**  
**Aurohealth LLC**

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**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:
  - headache
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - 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 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"> <li>• take 1 tablet every 8 to 12 hours while symptoms last</li> <li>• for the first dose you may take 2 tablets within the first hour</li> <li>• do not exceed 2 tablets in any 8 to 12 hour period</li> <li>• do not exceed 3 tablets in a 24 hour period</li> </ul>
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 58602-737-07  
Naproxen Sodium Tablets,  
USP 220 mg (NSAID)  
HEADACHE PAIN**

- ***Pain reliever***
- ***Fever reducer***

***For temporary relief of headache pain***  
**STRENGTH TO LAST 12 HOURS**  
**24 Tablets**

# Base



Booklet Placement

## Booklet

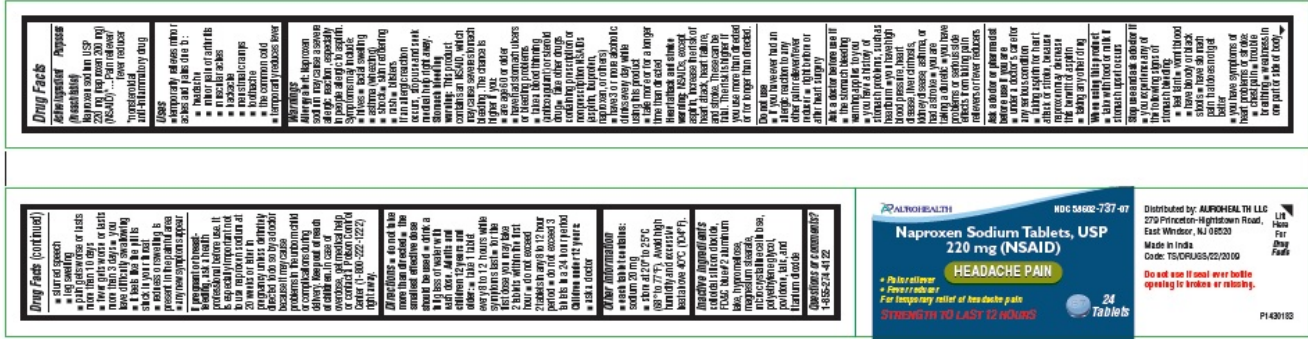
Page #2  
(Back of Cover)

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 58602-737-07**

**\*\*Compare to Aleve® Headache Pain**  
**active ingredient**  
**Naproxen Sodium Tablets, USP**

**220 mg (NSAID)**  
**HEADACHE PAIN**

- Pain reliever
- fever reducer

*For temporary relief*  
*of headache pain*

**STRENGTH TO LAST 12 HOURS**  
**24 Tablets**



## NAPROXEN SODIUM HEADACHE PAIN

naproxen sodium tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-737
<b>Route of Administration</b>	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--ALUMINUM LAKE (UNII: 4AQ3JLGS84)	

<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE 200</b> (UNII: 5XDI2TS1EZ)	
<b>POLYETHYLENE GLYCOL 8000</b> (UNII: Q662QK8M3B)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE (light blue)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Circular)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	J;67
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-737-07	1 in 1 CARTON	07/14/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-737-12	1 in 1 CARTON	07/14/2021	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-737-78	1 in 1 CARTON	07/14/2021	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-737-21	1 in 1 CARTON	07/14/2021	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-737-25	1 in 1 CARTON	07/14/2021	
5		130 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-737-29	1 in 1 CARTON	07/14/2021	
6		150 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-737-34	1 in 1 CARTON	07/14/2021	
7		200 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-737-38	1 in 1 CARTON	07/14/2021	
8		300 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-737-40	1 in 1 CARTON	07/14/2021	
9		500 in 1 BOTTLE; Type 0: Not a Combination Product		

<b>10</b>	NDC:58602-737-44	400 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2021
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205497	07/14/2021	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-737) , MANUFACTURE(58602-737)

Revised: 12/2023

Aurohealth LLC