NAPROXEN SODIUM HEADACHE PAIN - 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:
  - 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	• 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

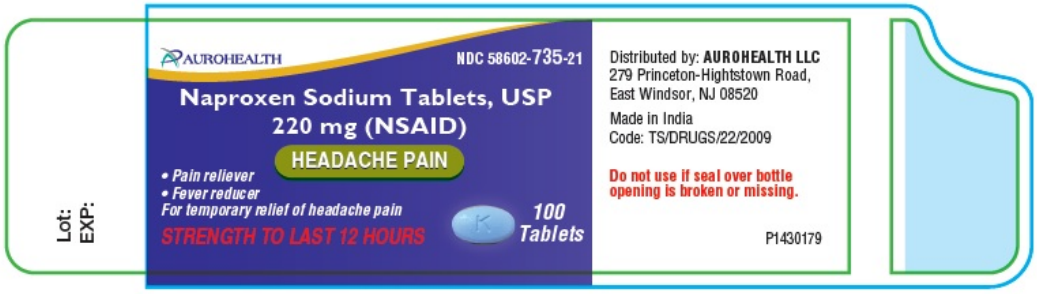
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (100 Tablets Bottle)

AUROHEALTH
NDC 58602-735-21
Naproxen Sodium Tablets, USP
220 mg (NSAID)
HEADACHE PAIN

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

For temporary relief of headache pain
STRENGTH TO LAST 12 HOURS
100
Tablets

Base



Booklet Placement

Booklet

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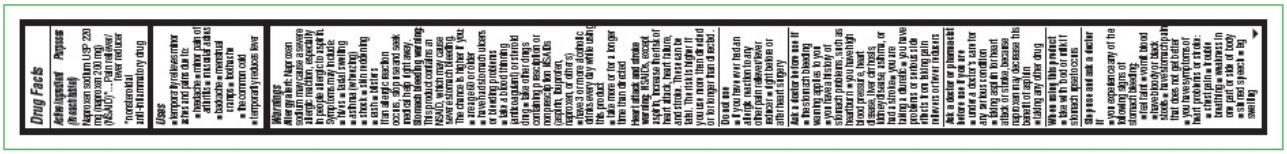
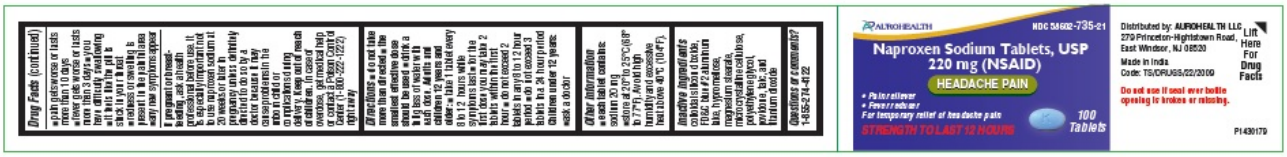
Back



Front



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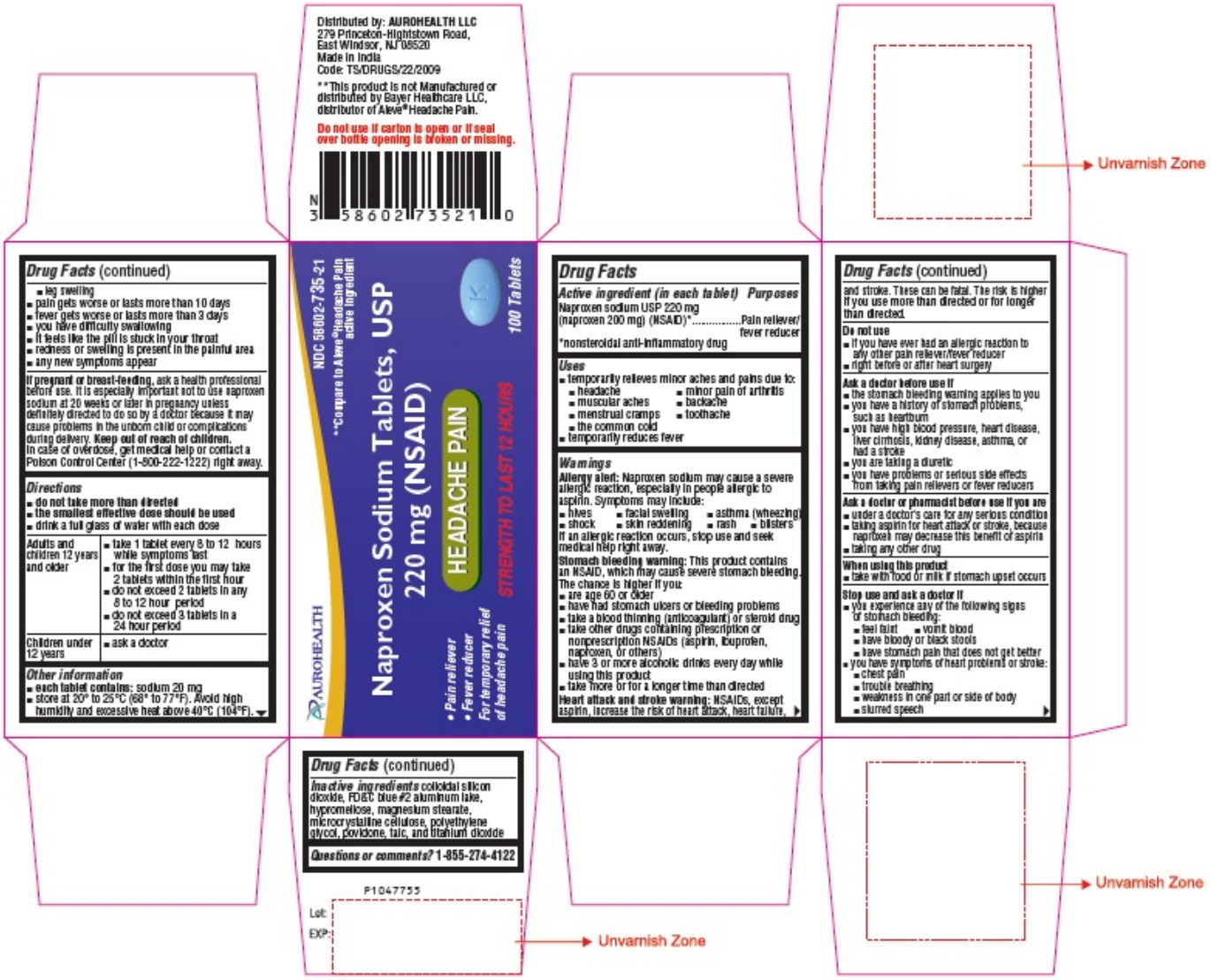
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg (100 Tablets Carton Label)

AUROHEALTH
NDC 58602-735-21
****Compare to Aleve® Headche 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
100 Tablets



NAPROXEN SODIUM HEADACHE PAIN

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-735
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--ALUMINUM LAKE (UNII: 4AQJ3LG584)	

HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 200 (UNII: 5XDI2TS1EZ)	
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	OVAL	**Size**	12mm
Flavor		**Imprint Code**	K;45
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-735-21	1 in 1 CARTON	07/14/2021	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-735-78	1 in 1 CARTON	07/14/2021	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-735-07	1 in 1 CARTON	07/14/2021	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-735-29	1 in 1 CARTON	07/14/2021	
4		150 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-735-38	1 in 1 CARTON	07/14/2021	
5		300 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-735-40	1 in 1 CARTON	07/14/2021	
6		500 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-735-19	1 in 1 CARTON	09/21/2023	
7		90 in 1 BOTTLE; Type 0: Not a Combination Product		

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(58602-735) , MANUFACTURE(58602-735)

Revised: 2/2025 Aurohealth LLC