NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE SINUS AND COLD - naproxen sodium and pseudoephedrine hydrochloride tablet, extended release
Aurohealth LLC

Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-Release Tablets, USP 220 mg/120 mg Sinus and Cold

Drug Facts

Active ingredients (in each caplet)

Naproxen sodium USP 220 mg (naproxen 200 mg) (NSAID)*
Pseudoephedrine Hydrochloride USP 120 mg, extended-release

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Nasal decongestant

Uses

temporarily relieves these cold, sinus, and flu symptoms:

- sinus pressure
- minor body aches and pains
- headache
- nasal and sinus congestion (promotes sinus drainage and restores freer breathing through the nose)
- 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
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- in children under 12 years of age

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, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, 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
  - redness or swelling is present in the painful area
  - any new symptoms appear
  - fever gets worse or lasts more than 3 days
  - you have difficulty swallowing or the caplet feels stuck in your throat
  - you get nervous, dizzy, or sleepless
  - nasal congestion lasts more than 7 days

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 right away. (1-800-222-1222)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- **swallow whole;** do not crush or chew
- **drink a full glass of water with each dose**
- adults and children 12 years and older: **1 caplet every 12 hours;** do not take more than 2 caplets in 24 hours
- children under 12 years: do not use

Other information

- **each caplet contains:** sodium 22 mg
- store at 20° to 25°C (68° to 77°F)
- store in a dry place

- FDA approved dissolution test specifications differ from USP.

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, ferric oxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc and titanium dioxide.

Questions or comments?

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

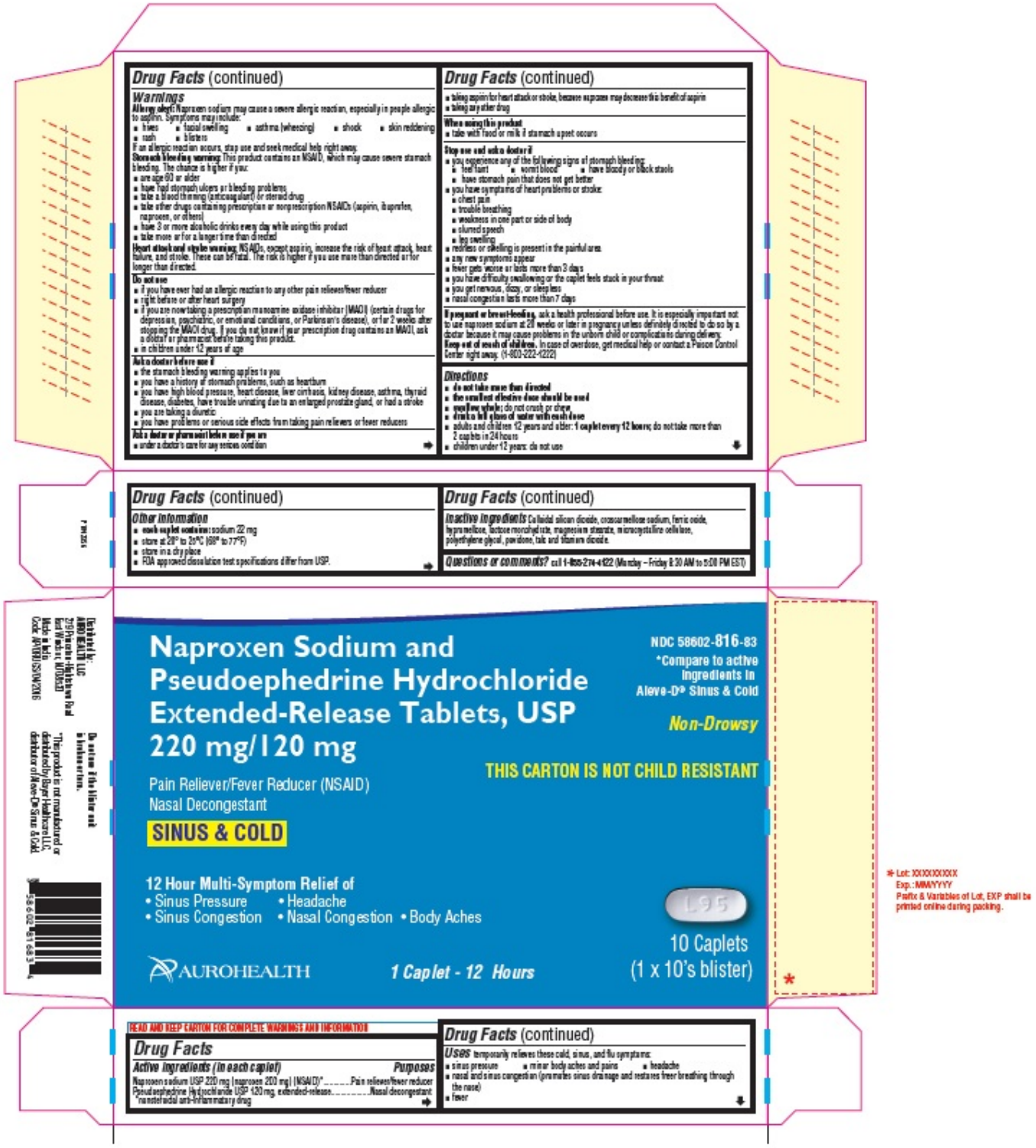
Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 220 mg / 120 mg 10 Caplets (Capsule-Shaped Tablets) Blister Carton Label

NDC 58602-816-83
***Compare to active ingredients in**
Aleve-D® Sinus & Cold
Non-Drowsy
THIS CARTON IS NOT CHILD RESISTANT
Naproxen Sodium and
Pseudoephedrine Hydrochloride
Extended-Release Tablets, USP
220 mg/120 mg
Pain Reliever/Fever Reducer (NSAID)
Nasal Decongestant
SINUS & COLD
12 Hour Multi-Symptom Relief of
- Sinus Pressure
- Headache
- Sinus Congestion
- Nasal Congestion
- Body Aches

10 Caplets
(1 x 10's blister)
1 Caplet - 12 Hours
AUROHEALTH



NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE SINUS AND COLD

naproxen sodium and pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-816
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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to off-white)	**Score**	no score
Shape	CAPSULE (Modified Capsule Shaped)	**Size**	17mm
Flavor		**Imprint Code**	L95
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-816-83	1 in 1 CARTON	06/01/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-816-67	2 in 1 CARTON	06/01/2022	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211360	06/01/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-816) , MANUFACTURE(58602-816)

Revised: 6/2022 Aurohealth LLC