NAPROXEN SODIUM - naproxen sodium capsule, liquid filled
Strides Pharma Inc

Naproxen Sodium Capsules, 220 mg, liquid filled

Drug Facts

Active Ingredient (in each capsule)

Naproxen sodium, 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
  - 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

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
- 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
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the capsule is stuck in your throat

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.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose
- if taken with food, this product may take longer to work

adults and children 12 years and older:	• take 1 capsule every 8 to 12 hours while symptoms last • for the first dose you may take 2 capsules within the first hour • do not exceed 2 capsules in any 8- to 12-hour period • do not exceed 3 capsules in a 24-hour period
children under 12 years:	• ask a doctor

Other information

- **each capsule contains:** sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- protect from light
- read all directions and warnings before use.

Inactive ingredients

FD & C Blue 1, gelatin, glycerin, lactic acid [racemic] [DM], polythene glycol 600, povidone-K-30, propylene glycol, purified water, sorbitol sorbitan solution.

printing ink white-edible oil - dewaxed bleached shellac resins, propylene glycol, sodium lauryl sulphate, titanium dioxide.

Questions or comments?

go to **www.strides.com** or call Strides Pharma Inc. weekdays from 9 AM to 5 PM EST at **1-877-244-9825**

Manufactured by:

Strides Pharma Science Limited

Bengaluru-562106, India.

Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

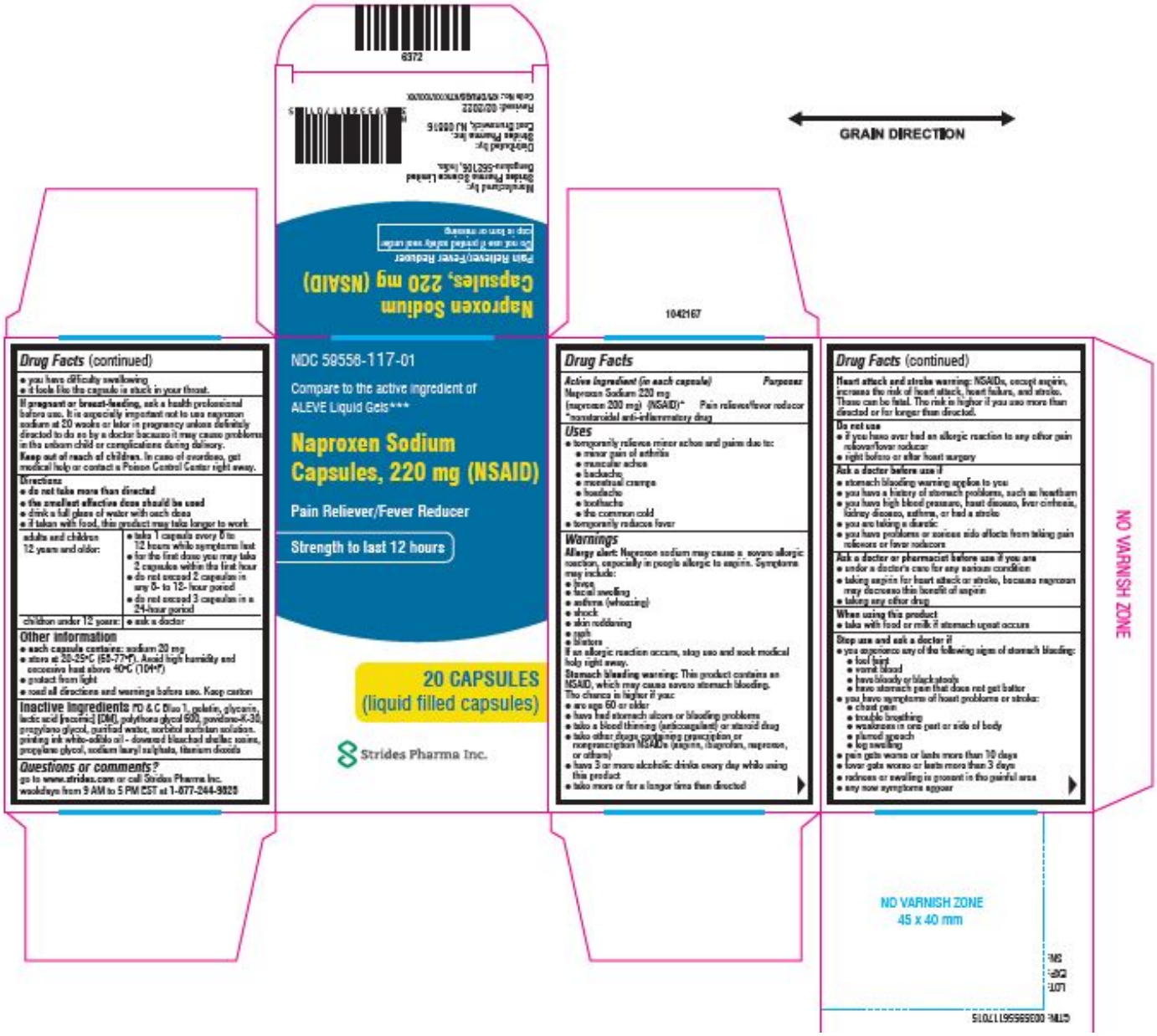
Do not use if printed safety seal under cap is torn or missing.

***This product is not manufactured or distributed by the owners of **ALEVE**® Liquid Gels.

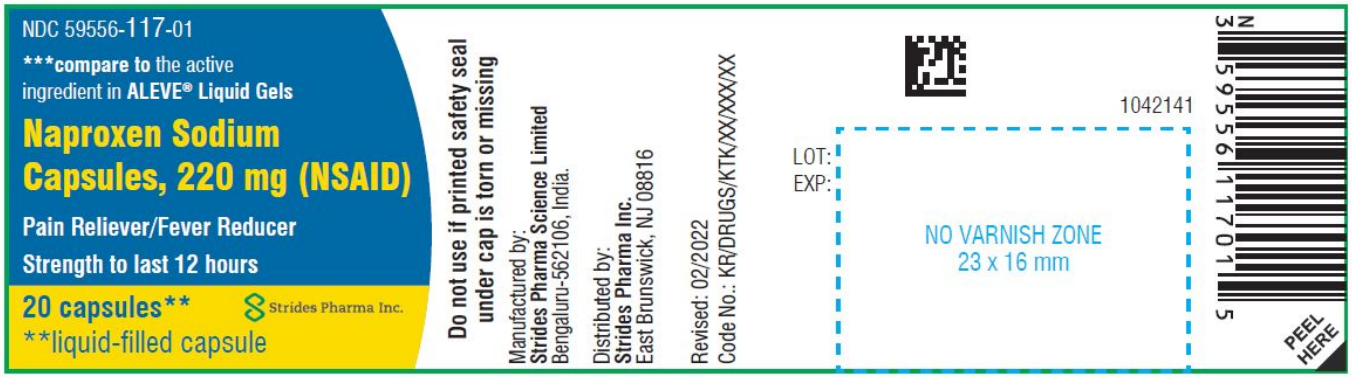
***__compare to__ the active ingredient in **ALEVE® Liquid Gels**

Issued: 06/2022

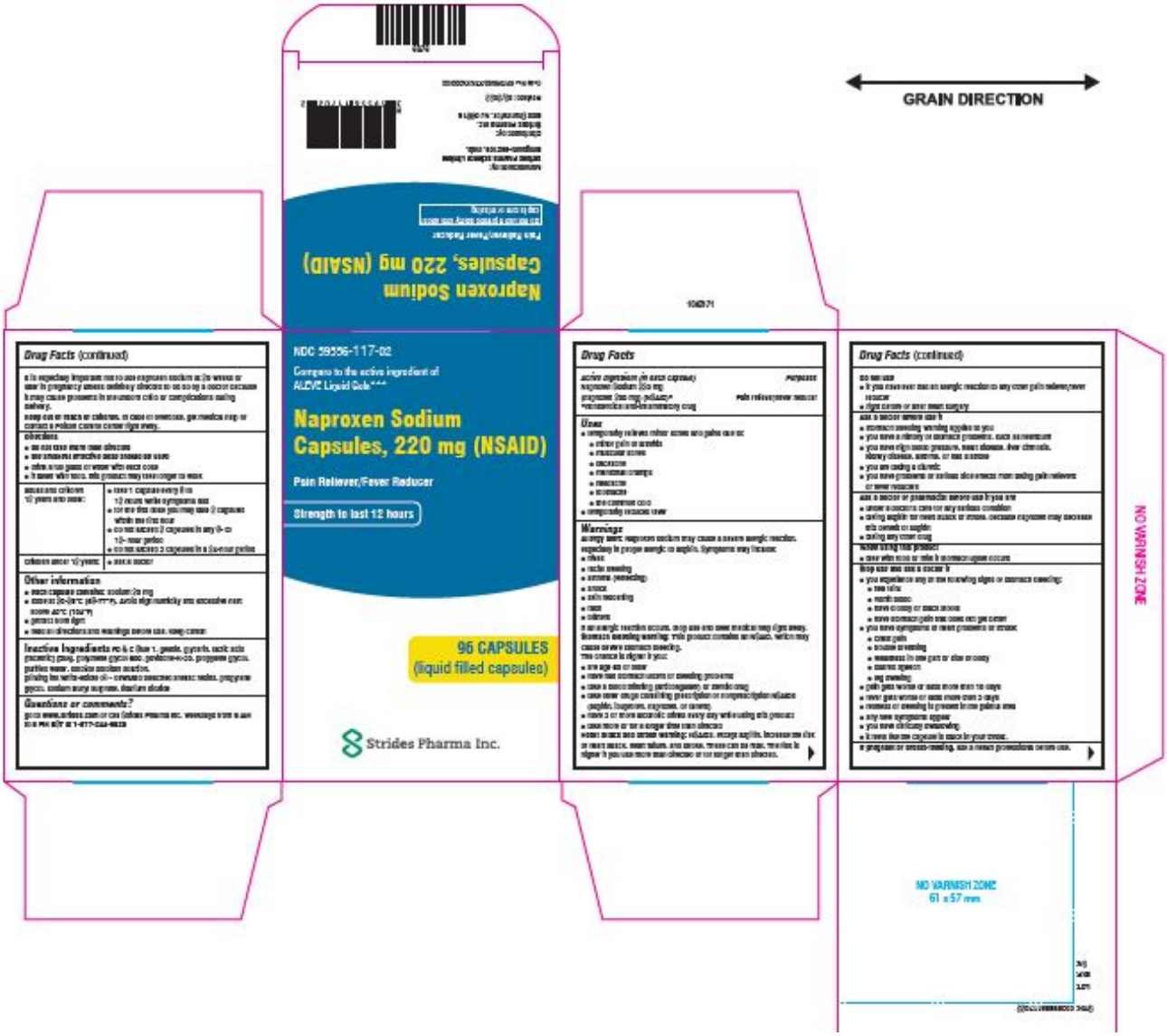
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



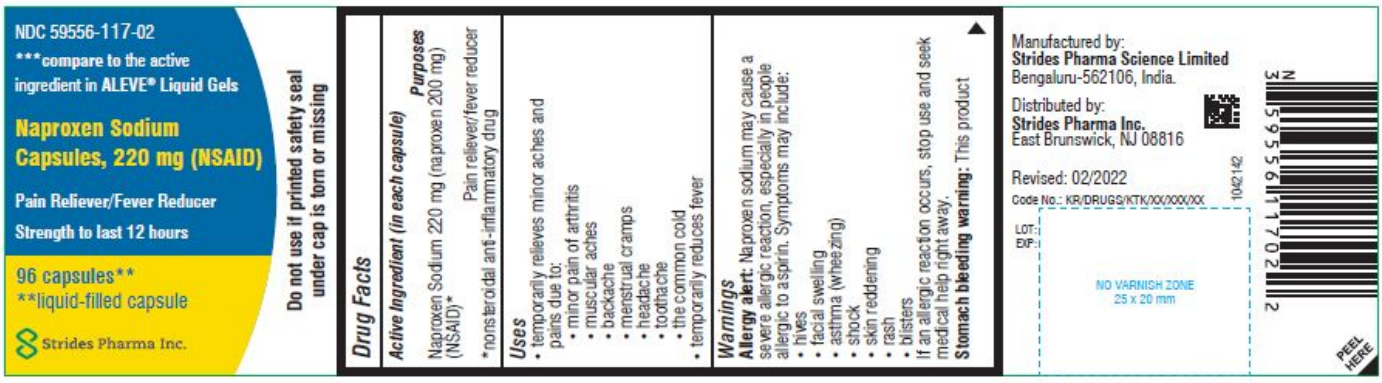
20s carton



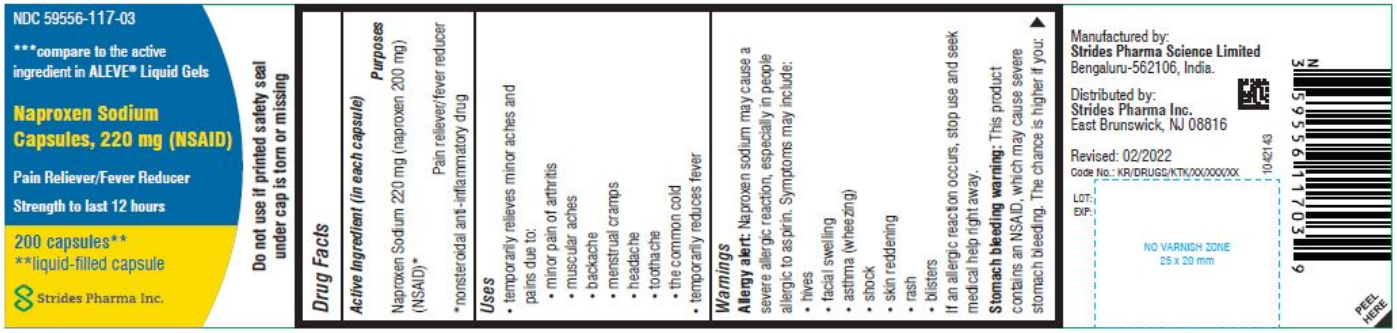
20s Container



96s Carton



96s Container



200s container

NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-117
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTIC ACID (UNII: 33X04XA5AT)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (Blue with white text)	**Score**	no score
Shape	OVAL (Oblong)	**Size**	21mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-117-02	1 in 1 CARTON	08/19/2024	
1		96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59556-117-03	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2024	
3	NDC:59556-117-01	1 in 1 CARTON	08/19/2024	
3		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215472	08/19/2024	

Labeler - Strides Pharma Inc (078868278)

Registrant - Strides Pharma Global Pte. Ltd. (659220961)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-117) , MANUFACTURE(59556-117) , PACK(59556-117)

Revised: 8/2022 Strides Pharma Inc