

ALEVE LIQUID GELS- naproxen sodium capsule, liquid filled
Bayer Healthcare LLC

ALEVE LIQUID GELS

Drug Facts

Active ingredient (in each capsule)

Naproxen Sodium 220mg (Naproxen 200mg) (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
 - slurred speech
 - weakness in one part or side of body
 - 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 ammonium hydroxide, FD&C blue #1, gelatin, glycerin, lactic acid, mannitol, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, purified water, sorbitan-sorbitol solution, titanium dioxide

Questions or comments? 1-800-395-0689
(Mon-Fri 9AM – 5PM EST)

PRINCIPAL DISPLAY PANEL - 160 Capsules Label

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 200 mg (**NSAID**)
Pain Reliever/Fever Reducer

ALEVE

**BAYER
STRENGTH TO
LAST 12 HOURS**

**160CAPSULES
LIQUID FILLED CAPSULES**

Do not use if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing. Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC Whippany, NJ 07981

LOT
EXP/MADE IN
Bayer

ALL DAY STRONG®
ALEVE®
LIQUID GELS
Naproxen Sodium Capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer

ALL DAY STRONG®
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LIQUID GELS
Naproxen Sodium Capsules, 220 mg (NSAID)
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STRENGTH TO LAST 12 HOURS

160 CAPSULES
LIQUID FILLED CAPSULES

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Drug Facts (continued)

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- 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

Drug Facts (continued)

- 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:
 - red or black stools
 - vomiting 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
 - slurred speech
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- any new symptoms appear
- you have difficulty swallowing
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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

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 ammonium hydroxide, FD&C blue #1, gelatin, glycerin, lactic acid, mannitol, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, purified water, sorbitan-sorbitol solution, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

PRINCIPAL DISPLAY PANEL - 20 Capsules Label

ALL DAY STRONG®

ALEVE®

LIQUID GELS

*naproxen sodium capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer*

BAYER

ALEVE

**STRENGTH TO
LAST 12 HOURS**

**20CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 20 Capsules Carton

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 220 mg **(NSAID)**
Pain Reliever/Fever Reducer

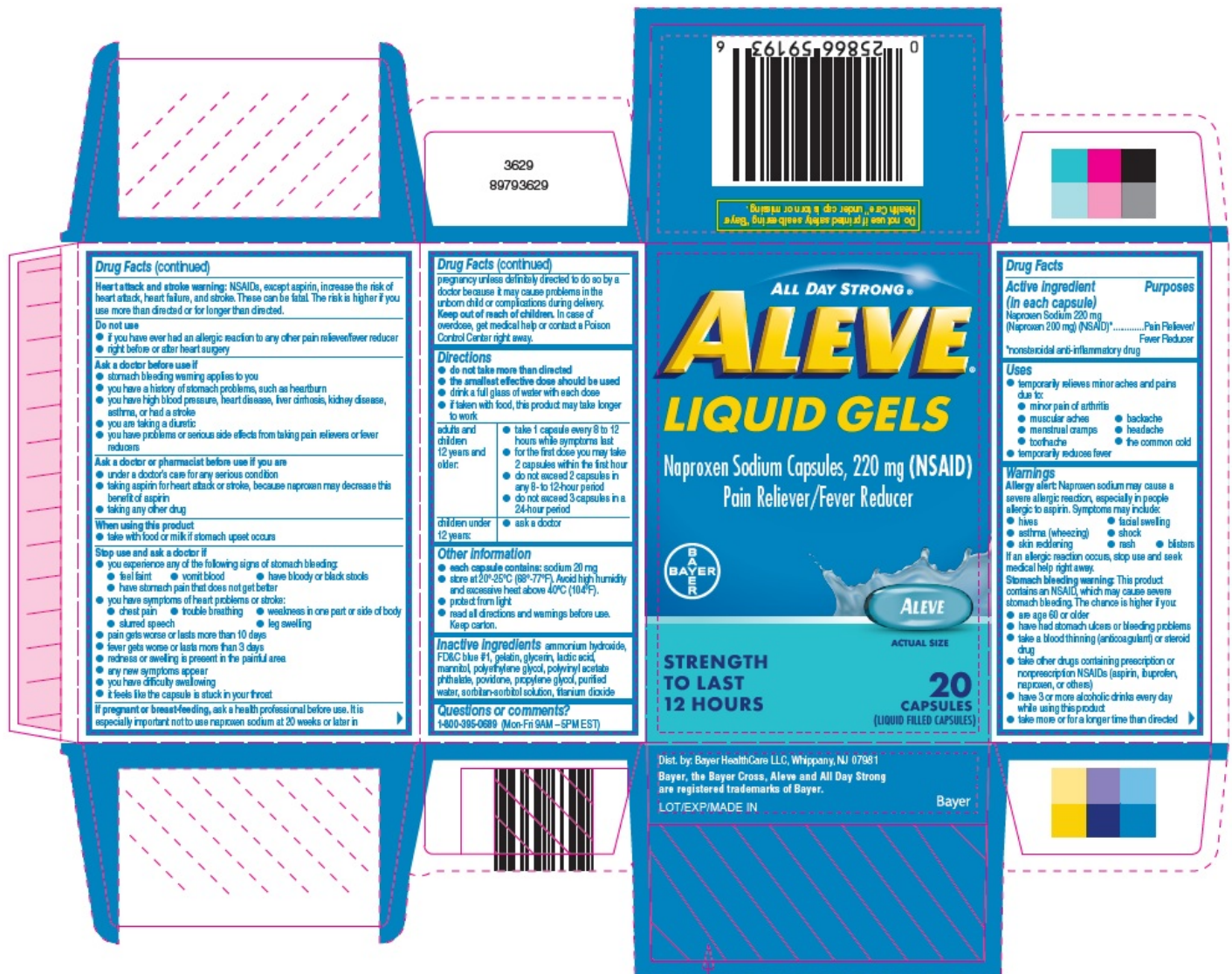
BAYER

ALEVE

ACTUAL SIZE

**STRENGTH
TO LAST
12 HOURS**

**20
CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 50 Capsules Label

ALL DAY STRONG®

ALEVE®

LIQUID GELS

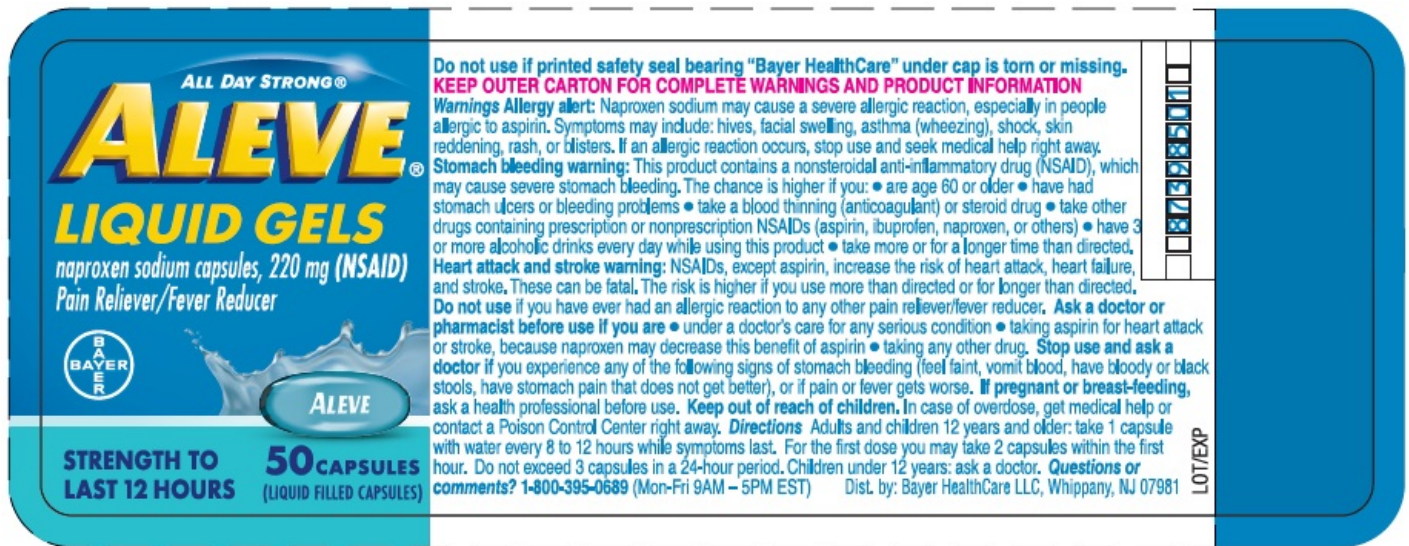
*naproxen sodium capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer*

BAYER

ALEVE

**STRENGTH TO
LAST 12 HOURS**

**50CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 50 Capsules Carton

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 220 mg **(NSAID)**
 Pain Reliever/Fever Reducer

BAYER

ALEVE

ACTUAL SIZE

**STRENGTH
 TO LAST
 12 HOURS**

**50
 CAPSULES
 (LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 80 Capsules Label

ALL DAY STRONG®

ALEVE®

LIQUID GELS

*naproxen sodium capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer*

BAYER

ALEVE

**STRENGTH TO
LAST 12 HOURS**

**80CAPSULES
(LIQUID FILLED CAPSULES)**

ALL DAY STRONG®
ALEVE®
LIQUID GELS
 naproxen sodium capsules, 220 mg (NSAID)
 Pain Reliever/Fever Reducer

BAYER

STRENGTH TO LAST 12 HOURS

80 CAPSULES
 (LIQUID FILLED CAPSULES)

Do not use if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION Warnings: **Always** alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, dizziness, rash, or trouble breathing. **Stop use and get medical help right away.** **Warnings:** Stomach and intestinal bleeding, ulcers, and perforation with or without warning symptoms (such as stomach pain, heartburn, or indigestion) may occur without warning symptoms. Stomach and intestinal bleeding, ulcers, and perforation may occur with or without warning symptoms. **Stop use and get medical help right away if you experience any of the following signs or symptoms:** • 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 warnings:** 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 or 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 disease, kidney disease, asthma, or had a stroke, you are using a diuretic, you have problems or serious side effects with taking prescription or nonprescription drugs, or you are taking aspirin for heart attack or stroke. **Warnings:** • **Stop use and get medical help right away if you experience any of the following signs or symptoms:** • 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 or symptoms:** • bleeding (red or black stool, 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, or it looks like the capsule is stuck in your throat. If pregnant or breast-feeding, ask a health professional before use. 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 help reduce stomach upset. **Usual Dosage:** Adults 12 years and older: Take 2 capsules 4 to 12 hours apart with water. **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. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). Protect from light. Questions or comments? **1-800-395-0889**
 (Mon-Fri 9AM - 5PM EST)
 Bayer HealthCare, LLC
 Whippany, NJ 07981
LOT/EXP

PRINCIPAL DISPLAY PANEL - 80 Capsules Carton

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 220 mg **(NSAID)**
 Pain Reliever/Fever Reducer

BAYER

ALEVE
ACTUAL SIZE

STRENGTH
TO LAST
12 HOURS

80
CAPSULES
(LIQUID FILLED CAPSULES)



PRINCIPAL DISPLAY PANEL - 80 Capsules Label

**EASY OPEN
ARTHRITIS CAP**

ALL DAY STRONG®

ALEVE®

LIQUID GELS

*naproxen sodium capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer*

**THIS PACKAGE FOR HOUSEHOLDS
WITHOUT YOUNG CHILDREN**

ALEVE

BAYER

**STRENGTH TO
LAST 12 HOURS**

**80CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 80 Capsules Carton

EASY OPEN ARTHRITIS CAP

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 220 mg **(NSAID)**
Pain Reliever/Fever Reducer

THIS PACKAGE FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN

BAYER

ALEVE

ACTUAL SIZE

**STRENGTH
TO LAST
12 HOURS**

**80
CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 120 Capsules Label

ALL DAY STRONG®

ALEVE®

LIQUID GELS

*naproxen sodium capsules, 220 mg (NSAID)
Pain Reliever/Fever Reducer*

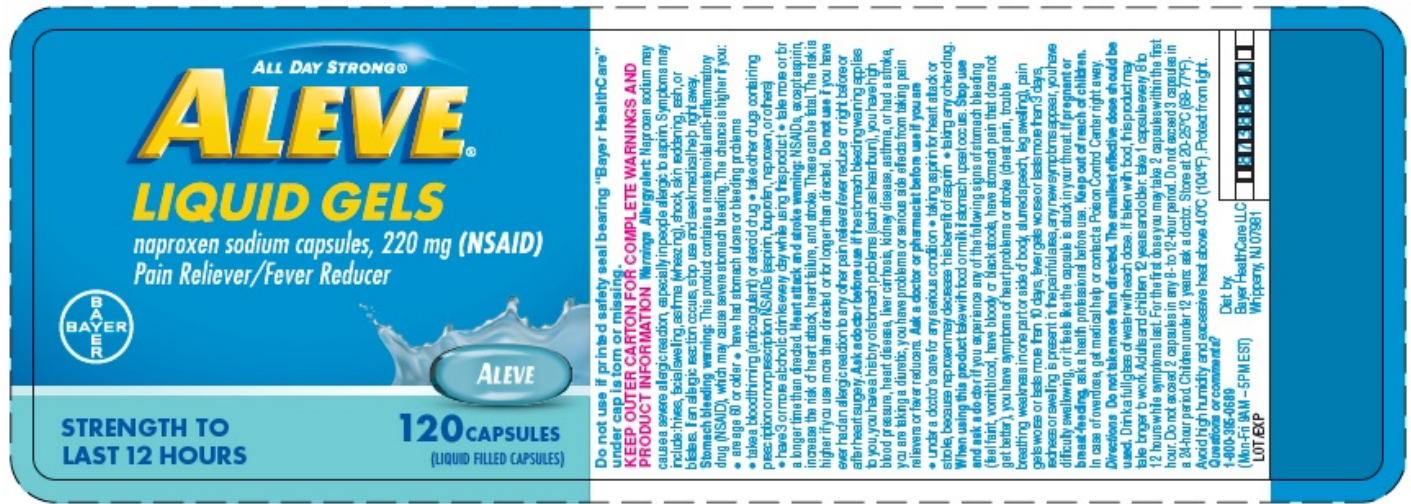
BAYER

ALEVE

STRENGTH TO

LAST 12 HOURS

**120CAPSULES
(LIQUID FILLED CAPSULES)**



PRINCIPAL DISPLAY PANEL - 120 Capsules Carton

**120
LIQUID FILLED CAPSULES**

ALL DAY STRONG®

ALEVE®

LIQUID GELS

Naproxen Sodium Capsules, 220 mg **(NSAID)**
Pain Reliever/Fever Reducer

BAYER

ALEVE

ACTUAL SIZE

**STRENGTH
TO LAST
12 HOURS**

**120
CAPSULES
(LIQUID FILLED CAPSULES)**



ALEVE LIQUID GELS

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0105
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
AMMONIA (UNII: 5138Q19F1X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Blue with white text)	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	P797
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0105-02	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2023	
2	NDC:0280-0105-03	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/07/2024	
3	NDC:0280-0105-04	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2024	
4	NDC:0280-0105-05	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2024	
5	NDC:0280-0105-06	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2024	
6	NDC:0280-0105-01	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214463	12/01/2023	

Registrant - Bayer Healthcare LLC (072827066)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(0280-0105)

Revised: 5/2024

Bayer Healthcare LLC