# TOPCARE ALL DAY PAIN RELIEF- naproxen sodium tablet, film coated Topco Associates LLC

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# Topco Associates LLC. All Day Pain Relief Drug Facts

### Active ingredient (in each caplet)

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

- 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 during the last 3 months of 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
- drink a full glass of water with each dose

Adults and children 12 years and older	<ul> <li>take 1 caplet every 8 to 12 hours while symptoms last</li> <li>for the first dose you make take 2 caplets within the first hour</li> <li>do not exceed 2 caplets in any 8- to 12-hour period</li> <li>do not exceed 3 caplets in a 24-hour period</li> </ul>
Children under 12 years	ask a doctor

#### Other information

- each caplet contains: sodium 22 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

# **Inactive ingredients**

FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

## **Questions or comments?**

#### 1-888-423-0139

# **Principal Display Panel**

TopCare<sub>®</sub> health

COMPARE TO ALEVE® ACTIVE INGREDIENT

All Day Pain Relief

NAPROXEN SODIUM TABLETS, 220 mg EACH

PAIN RELIEVER - FEVER REDUCER (NSAID)

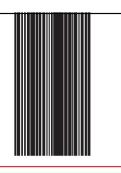
12 HOUR

Strength to last 12 hours

200 CAPLETS†

**†CAPSULE-SHAPED TABLETS** 

actual size



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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

**GLUTEN FREE** 

**✓QUALITY GUARANTEED** 

#### Drug Facts (continued)

- 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
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   you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke vou 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 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

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  # have stomach pain that does not get better

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- while symptoms last
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- 8- to 12-hour period

  do not exceed 3 caplets in a 24-hour period
- Children under 12 years ask a doctor

#### Other information

- each caplet contains: sodium 22 mg
   store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- Inactive ingredients FD&C blue no. 2 aluminum lake, hypromellose, magnesium ster microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-888-423-0139

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

# TopCare.

86800-368-82

COMPARE TO ALEVE® ACTIVE INGREDIENT\*\*

# **All Day Pain Relief**

NAPROXEN SODIUM TABLETS. 220 mg EACH

PAIN RELIEVER • FEVER REDUCER (NSAID)



#### Drug Facts

Active ingredient (in each caplet)
Naproxen sodium 220 mg
(naproxen 200 mg) (NSAID)\*....\*
\*nonsteroidal anti-inflammatory drug

Purposes Pain reliever fever reduce

#### Uses

- temporarily relieves minor aches and pains due to:
- minor pain of arthritis
   muscular aches
   menstrual cramps
- toothache

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Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

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  skin reddening

  rash

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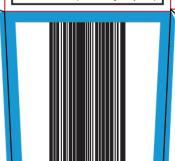
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KEEP PACKAGE FOR REFERENCE

actual size

36882 88 C10

#### **TOPCARE ALL DAY PAIN RELIEF**

naproxen sodium tablet, film coated

#### **Product Information**

**Product Type HUMAN OTC DRUG** Item Code (Source) NDC:36800-368

**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. 2 (UNII: L06K8R7DQK)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	BLUE (Light Blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	L368
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-368- 62	1 in 1 CARTON	07/22/1997	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-368- 71	1 in 1 CARTON	01/14/1997	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:36800-368- 78	1 in 1 CARTON	06/11/2002	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:36800-368- 82	1 in 1 CARTON	01/27/2004	
4		200 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:36800-368- 76	1 in 1 CARTON	06/29/2007	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:36800-368- 79	400 in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2019	
7	NDC:36800-368- 75	1 in 1 CARTON	07/12/2022	
7		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing	Application Number or Monograph Citation	Marketing Start	Marketing End	
Category		Date	Date	

ANDA	ANDA074661	01/14/1997	

# Labeler - Topco Associates LLC (006935977)

Revised: 7/2022 Topco Associates LLC