## ALL DAY PAIN RELIEF- naproxen sodium capsule, liquid filled Harmon Stores

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#### **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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time 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, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

#### Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug

#### When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- 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 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.

#### 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
- swallow whole; do not crush, chew or dissolve
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

#### **Inactive ingredients**

FD&C blue #1, gelatin, glycerin, lactic acid, mannitol, pharmaceutical ink, polyethylene glycol 600, povidone K30, propylene glycol, purified water, sorbitan, sorbitol

#### Questions or comments?

Call 1-877-153-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

Compare ours to the active ingredient in Aleve® Liquid Gels†

#### **All Day Pain Relief**

Naproxen sodium capsules 220 mg (NSAID\*)

Pain reliever/fever reducer

For 8-12 hours of relief

Liquid gels (liquid filled capsules)

†This product is not manufactured or dostributed by Bayer HealthCare, LLC., owner of the registered trademark Aleve® Liquid Gels.

Dsitributed by

Harmon Stores, Inc

650 Liberty Ave

Union, NJ 07083 USA

www.facevalues.com

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

#### **Product Label**

Exp. Date:

Lot No.:

PLD-A337A FC002533

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## **Drug Facts** (continued)

you have high blood pressure, heart disease, liver cirrhosis. or

Purposes fever reducer

Active ingredient (in each capsule)

**Orug Facts** 

- you have problems or serious side effects from taking pain relievers or fever reducers you are taking a diuretic
  - you have asthma

Ask a doctor or pharmacist before use if you are under a doctor's care for any serious condition

temporarily relieves minor aches and pains due to:

Naproxen Sodium Capsules,

FOR 8 - 12 HOURS OF RELIEF

menstrual cramps

temporarily reduces fever

the common cold

muscular aches

minor pain of arthritis

taking any other drug

■ take with food or milk if stomach upset occurs

the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

 you experience any of the following signs of stomach bleeding: Stop use and ask a doctor if

feel faint

 vomit blood ■ have bloody or black stools ■ vomit ble
■ have stomach pain that does not get better
■ pain gets worse or lasts more than 10 days

fever gets worse or lasts more than 3 days
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asthma (wheezing)

 facial swelling shock skin reddening

FACE VALUES

(NSAID\*)

rash = bisters

 take other drugs containing prescription or nonprescription NSAIDs have 3 or more alcoholic drinks every day while using this product

take a blood thinning (anticoagulant) or steroid drug

have had stomach ulcers or bleeding problems

are age 60 or older

 you have difficulty swallowing any new symptoms appear

it feels like the capsule is stuck in your throat

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If you have ever had an altergic reaction to any other pain

right before or after heart surgery

relever/fever reducer

Ask a doctor before use if

40 LIQUID GELS (Liquid Filled Capsules)

Actual Size

take more or for a longer time than directed (aspirin, buprofen, naproxen, or others)

Do not use

- the smallest effective dose should be used do not take more than directed
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   children under 12 years; ask a doctor

## Other information

- each capsule contains: sodium 20 mg
   swallow whole; do not crush, chew, or dissolve
   store at 20-25°C (88-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #1, gelatin, glycerin, lactic read all directions and warnings before use. Keep carton.

povidone K30, propylene glycol, purified water, sorbitan, sorbital acid, mannitol, pharmaceutical ink, polyethylene glycol 600,

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

This product is not manufactured or distributed by Bayer HealthCare, LLC., owner of the registered trademark Aleve® Liquid Gels.

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FREE AREA

220 mg

#### Harmon All Day Pain Relief Softgels

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

naproxen sodium capsule, liquid filled

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-174

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength

NAPRO XEN SO DIUM (UNII: 9TN87S3A3C) (NAPRO XEN - UNII:57Y76R9 ATQ) NAPRO XEN SO DIUM 220 mg

#### **Inactive Ingredients**

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
PO VIDO NE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	

#### **Product Characteristics**

SORBITOL (UNII: 506T60A25R)

Color	BLUE	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	NPX
Contains			

Packaging

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:63940-174-	1 in 1 BOX	07/31/2015	12/31/2020	
1	40 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	
NDA	NDA021920	07/31/2015	12/31/2020	

### Labeler - Harmon Stores (804085293)

Revised: 11/2019 Harmon Stores