### NAPROXEN SODIUM- naproxen sodium capsule, liquid filled McKesson (Health Mart)

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**Drug Facts** 

Active ingredient (in each capsule)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)\*

\*nons teroidal 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

**Heart attack and stroke:** 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 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
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - slurred speech
  - leg swelling
  - trouble breathing
  - weakness in one part or side of body
- 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 (1-800-222-1222) 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:
  - o take 1 capsule every 8 to 12 hours while symptoms last
  - o 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).
- read all directions and warnings before use. Keep carton.
- swallow whole; do not crush, chew, or dissolve

#### **Inactive ingredients**

FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone K30, propylene glycol, purified water, shellac glaze, sorbitan, sorbitol solution, titanium dioxide, white ink

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

Compare to the active ingredient in Aleve®†

Naproxen Sodium Capsules, 220 mg

Pain Reliever/Fever Reducer (NSAID)

#### Strength to Last 12 Hours

Liquid Gels\*\*

(\*\*Liquid-filled capsules)

†This product is not manufactured or distributed by Bayer HealthCare, LLC distributor of Aleve®

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

### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION $\mathbf{M}^{C}$ KESSON

**Another Quality Product** 

Distributed by McKesson

6555 State Highway 161 Irving, TX 75039

healthmart.com

#### **Product Label**

Lot No.

PLD-C5288 FC004884

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Another Quality Product
Distributed by McKesson
6555 State Highway 161 Inving, TX 75039
Money Back Guarantee

## MCKESSON

## Orug Facts (continued)

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# right before or after heart surgery

- Ask a doctor before use if
- The stornach 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
- you have problems or serious side effects from taking pain you are taking a duretic
- relievers or fever reducers
- Ask a doctor or pharmacist before use if you are under a doctor's care for any serious condition
- When using this product, take with food or milk if stomach upset taking any other drug

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

- have stomach pain that does not get better have bloody or black stools feel faint womit blood
- you have symptoms of heart problems or stroke ■ leg swelfing ■ brouble breathing sirred speech chest pain
  - pain gets worse or lasts more than 10 days weakness in one part or side of body
    - 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

by a doctor because it may cause problems in the unborn child or the last 3 months of pregnancy unless definitely directed to do so if pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during complications during delivery.

## Orug Facts (continued)

Keep out of reach of children, in case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222)

## Directions - do not take more than directed The smallest effective dose should be used

- If taken with food, this product may take longer to work drink a full glass of water with each dose
- 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 adults and children 12 years and older.
  - do not exceed 3 capsules in a 24-hour period

# children under 12 years: ask a doctor

store between 20-25°C (68-77°F). Avoid high furnidity and each capsule contains: sodium 20 mg Other information

 read all directions and warnings before use. Keep carton. excessive heat above 40°C (104°F).

swallow whole; do not crush, chew, or dissolve

Inactive ingredients FD&C blue #1, gelatin, glycerin, lactic acid, lectitiin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, thanlum dioxide, white ink

Duestions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

## **Drug Facts**

### Pain reliever/ fever reducer Purposes Vaproven sodium 220 mg (in each capsule) Active ingredien

(naproxen 200 mg) (NSAID)\* \*nonsteroidal anti-inflammatory drug

 temporarily relieves minor aches and pains due to: minor pain of arthritis backache

 menstrual cramps muscular aches toothache

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

temporarily reduces fever

The common cold

Health Mart.

f an allergic reaction occurs, stop use and seek medical help right asthma (wheezing) rash
 blisters facial swelling skin reddening

Stomach bleeding warning: This product contains an NSAID

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 take other drugs containing prescription or nonprescription take a blood thinning (anticoagulant) or steroid drug have had stomach ulcers or bleeding problems

NSAIDs (aspirin, ibuprofen, naproxen, or others)

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 have 3 or more alcoholic drinks every day while using this take more or for a longer time than directed

NDC 62011-0369-1

onger than directed

220 MG EACH

Compare to the active ingredient in Aleve®†

### Naproxen Sodium

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

Strength to Last 12 Hours

40 Liquid Gels\*\* (\*\*Liquid-filled capsules)

#### HEALTH MART Naproxen Sodium Capsules 220 mg

#### NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:62011-0369

Route of Administration ORAL

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

0	J			
	Ingredient Name		Basis of Strength	Strength
NAPRO XEN SODIUM (UNII:	9TN87S3A3C) (NAPROXEN - UI	NII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46 N10 7B71O)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	20 mm	
Flavor		Imprint Code	PC19	
Contains				

]	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:62011-0369-	1 in 1 BOX	0 4/0 1/20 18	
	L	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	
ANDA	ANDA208363	0 4/0 1/20 18		

### Labeler - McKesson (Health Mart) (177667227)

Revised: 6/2019 McKesson (Health Mart)