

ALL DAY PAIN RELIEF- naproxen sodium tablet, film coated
Family Dollar Services Inc

Family Wellness 44-604

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - the common cold
 - toothache
 - menstrual cramps
 - backache
 - minor pain of arthritis
- temporarily reduces fever

Warnings

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

- asthma (wheezing)
- skin reddening
- shock
- blisters
- rash
- facial swelling
- hives

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

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

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
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke
 - leg swelling
 - chest pain
 - slurred speech
 - 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
- 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 (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
- adults and children 12 years and older
 - take 1 caplet every 8 to 12 hours while symptoms last
 - for the first dose you may take 2 caplets within the first hour
 - do not exceed 2 caplets in any 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 20 mg
- store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal display panel

COMPARE TO THE ACTIVE INGREDIENT OF ALEVE® CAPLETS†

FAMILY
wellness™

NDC 55319-604-12

STRENGTH TO LAST 12 HOURS

All Day Pain Relief

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

100 CAPLETS

ACTUAL SIZE

OTC
network

100% SATISFACTION GUARANTEED
OR YOUR MONEY BACK

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

50844 REV0517A60412

DISTRIBUTED BY:
MIDWOOD BRANDS, LLC
10611 MONROE RD.
MATTHEWS, NC 28105

NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

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

Drug Facts (continued)

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.

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Inactive ingredients cossamulose sodium, F0&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

Questions or comments?
Call 1-800-426-6393 8:30 AM-4:00 PM ET, Monday-Friday

This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark ALEVE® Caplets.
SKU 0902330
REV0517A60412
59844

COMPARE TO THE ACTIVE INGREDIENT OF ALEVE® CAPLETS!
NDC 55319-604-12

FAMILY wellness™

STRENGTH TO LAST 12 HOURS

All Day Pain Relief
Naproxen Sodium Tablets, 220 mg
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100 CAPLETS

100% SATISFACTION OR YOUR MONEY BACK GUARANTEED

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SKU 0902330

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No Print / No Varnish Lot no. & Exp. date

Drug Facts **KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

Active ingredient Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) **Purpose** Pain reliever/fever reducer, nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - the common cold
 - toothache
 - menstrual cramps
 - backache
 - minor pain of arthritis
- temporarily reduces fever

Warnings

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

- asthma (wheezing)
- skin redening
- 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 other drugs containing aspirin or steroid drug
 - take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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.

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

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
 - vomit blood
 - have bloody or black stools
- you have symptoms of heart problems or stroke
- belly swelling
- trouble breathing
- weakness in one part or side of body
- pain gets worse or lasts more than 3 days
- fever gets worse or lasts more than 10 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the genital area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen

Family Wellness 44-604

ALL DAY PAIN RELIEF

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-604
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	44;604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-604-12	1 in 1 CARTON	01/23/2017	
1		100 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	ANDA204872	01/23/2017	

Labeler - Family Dollar Services Inc (024472631)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55319-604)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55319-604)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(55319-604)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55319-604)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(55319-604)

Revised: 1/2020

Family Dollar Services Inc