NAPROXEN- naproxen sodium tablet, film coated
L.N.K. International, Inc.

Quality Plus 44-746

Active ingredient (in each tablet)

Naproxen Sodium USP 220 mg
(Naproxen 200 mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains due to

- minor pain of arthritis
- menstrual cramps
- backache
- toothache
- muscular aches
- headache
- 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:

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

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 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 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 for more than 10 days
- fever gets worse or lasts for 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 accidental 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

Adults and children 12 years and over:	■ Take 1 tablet every 8 to 12 hours while symptoms persist. ■ For the first dose you may take 2 tablets within the first hour. ■ Do not exceed 2 tablets in any 8 to 12 hour period. ■ Do not exceed 3 tablets in a 24 hour period.
Children under 12 years:	Ask a doctor.

Other information

- **each tablet contains:** sodium 20 mg
- store at room temperature 68°-77°F (20°-25°C)
- avoid high humidity and excessive heat above 104°F (40°C)
- tamper evident sealed packets
- do not use any open or torn packets

Inactive ingredients

croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

QUALITY

+ PLUS

NDC 50844-271-43

†Compare to active ingredient
in Aleve® Tablets

NAPROXEN
NAPROXEN SODIUM USP, 220 mg

PAIN RELIEVER/
FEVER REDUCER (NSAID)

60 Packets
of 1 Tablet each
220 mg each

ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF PACKET IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

†This product is not manufactured or distributed by
Bayer HealthCare LLC, owner of the registered
trademark Aleve® Tablets.
50844 ORG
Distributed by
LNK INTERNATIONAL, INC.
60 Arkay Drive
Hauppauge, NY 11788
USA

Quality Plus 44-746

NAPROXEN

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-271
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 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	I3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-271-43	60 in 1 CARTON	09/12/2019	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	09/12/2019	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(50844-271)

Revised: 12/2023 L.N.K. International, Inc.