NAPROXEN BACK AND MUSCLE PAIN- naproxen sodium tablet, film coated
L.N.K. International, Inc.

Quality Plus 44-417 Back and Muscle Pain

Active ingredient (in each tablet)

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:
  - backache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - the common cold
  - menstrual cramps
  - headache
- temporarily reduces fever

Warnings

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

- hives
- shock
- rash
- blisters
- skin reddening
- 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

- have had stomach ulcers or bleeding problems
- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed
- 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

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 are taking a diuretic
- 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

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:
  - weakness in one part or side of body
  - leg swelling
  - chest pain
  - slurred speech
  - trouble breathing
- pain gets worse or lasts more than 10 days
- you have difficulty swallowing
- any new symptoms appear
- fever gets worse or lasts more than 3 days
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area

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 tablet every 8 to 12 hours while symptoms last
  - 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 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)
- use by expiration date on package

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

QUALITY
+PLUS

NDC 50844-714-16

†Compare to
active ingredient in
Aleve® Back & Muscle
Pain Tablets

NAPROXEN
BACK AND MUSCLE PAIN

NAPROXEN SODIUM
TABLETS, 220 mg

PAIN RELIEVER/FEVER
REDUCER **(NSAID)**

For temporary relief of minor back
and muscle aches and pains

Strength to last 12 hours

1000
Coated Tablets

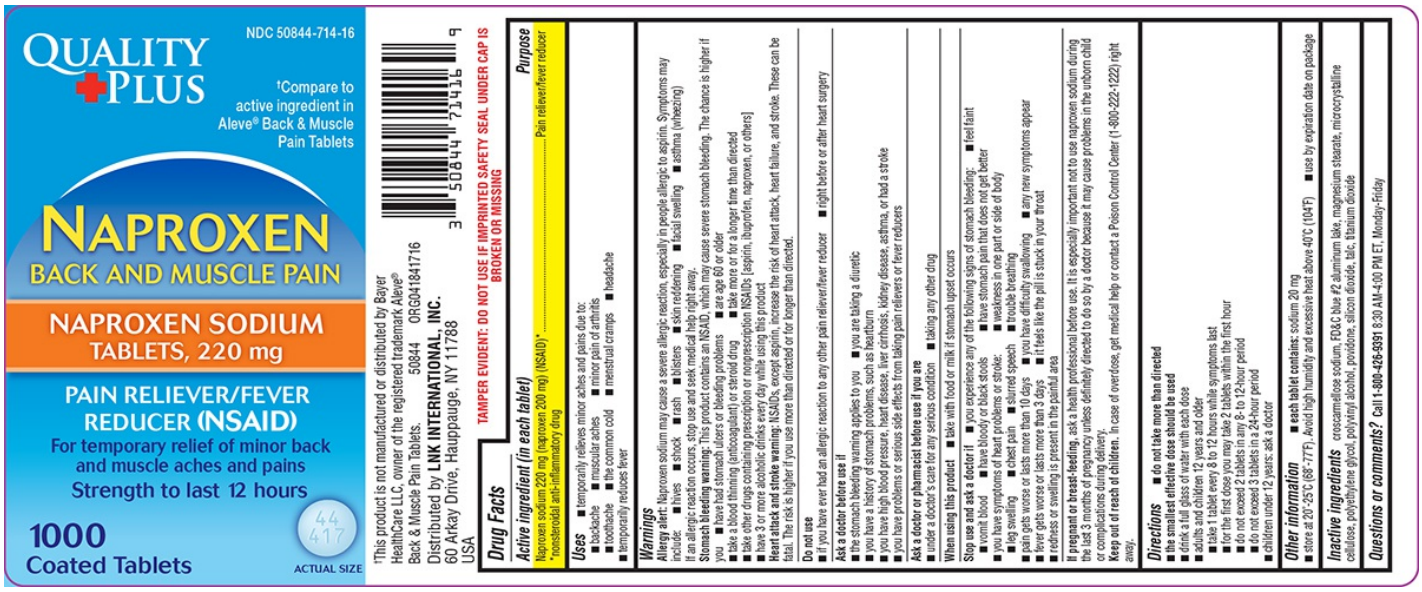
ACTUAL SIZE

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

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

Back & Muscle Pain Tablets. 50844 ORG041841716

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive, Hauppauge, NY 11788
USA



Quality Plus 44-417BM

NAPROXEN BACK AND MUSCLE PAIN

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-714
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: 3WQ0SDW1A)	
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	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;417
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-714-19	1 in 1 CARTON	02/01/2019	
1		8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50844-714-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	
3	NDC:50844-714-16	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	
4	NDC:50844-714-56	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	
5	NDC:50844-714-98	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	
6	NDC:50844-714-99	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	02/01/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-714)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-714)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-714)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-714)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-714)

Revised: 9/2019

L.N.K. International, Inc.