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

Quality Plus 44-417 and 44-604

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:
  - headache
  - muscular aches
  - minor pain of arthritis
  - toothache
  - the common cold
  - menstrual cramps
  - backache
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- 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
- 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 at 20 weeks or later in 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
- 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
- use by expiration date on package
- store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)

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

Active ingredient (in each caplet)

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*nonsteroidal anti-inflammatory drug

Purpose

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Uses

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  - headache
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  - the common cold
  - toothache
  - backache
  - menstrual cramps
  - 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

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- 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 are taking a diuretic
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

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Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
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- you have symptoms of heart problems or stroke:
  - slurred speech
  - trouble breathing
  - leg swelling
  - weakness in one part or side of body
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- pain gets worse or lasts more than 10 days
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- you have difficulty swallowing
- it feels like the pill is stuck in your throat
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- any new symptoms appear

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ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in 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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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
- 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
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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

QUALITY
+PLUS

NDC 50844-417-16

†Compare to
active ingredient
in Aleve® Tablets

NAPROXEN
SODIUM
TABLETS, 220 mg

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

STRENGTH TO LAST
12 HOURS

1000
Coated Tablets

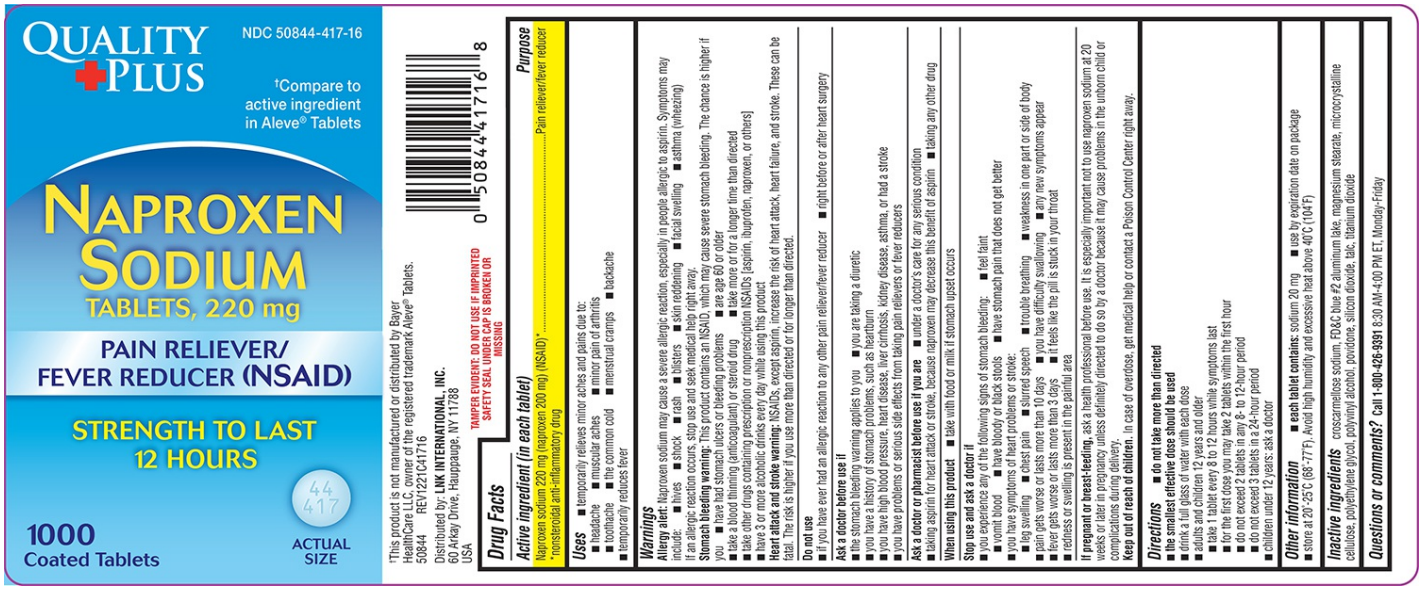
ACTUAL
SIZE

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® Tablets.
50844 REV1221C41716

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



Quality Plus 44-417

Principal display panel

QUALITY
+PLUS

NDC 50844-604-09

†*Compare to the active ingredient*
in Menstridol ®

NAPROXEN SODIUM
TABLETS, 220 mg

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

UP TO 12 HOURS OF MENSTRUAL PAIN RELIEF

Temporarily relieves minor cramps, backache, headache

20 Coated Caplets**
***CAPSULE-SHAPED TABLETS*

ACTUAL
SIZE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT 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 Menstridol®. 50844 REV1221C60409

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

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-417
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:50844-417-99	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
2	NDC:50844-417-98	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
3	NDC:50844-417-19	1 in 1 CARTON	02/01/2017	
3		8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:50844-	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	02/01/2017	

4	417-56	Product	02/01/2017	
5	NDC:50844-417-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
6	NDC:50844-417-16	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	02/01/2017	

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-604
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: 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	OVAL	**Size**	12mm
Flavor		**Imprint Code**	44;604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-604-99	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
2	NDC:50844-604-98	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
3	NDC:50844-604-19	1 in 1 CARTON	02/01/2017	
3		8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:50844-604-56	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
5	NDC:50844-604-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
6	NDC:50844-604-16	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2017	
7	NDC:50844-604-09	4 in 1 CARTON	02/01/2017	
7		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	02/01/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(50844-417, 50844-604)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(50844-417, 50844-604) , pack(50844-604)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(50844-417, 50844-604)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(50844-417, 50844-604)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(50844-417, 50844-604)