

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

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**Quality Plus 44-417 Headache 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:
  - 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:
  - 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 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
- 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 50844-471-16

†Compare to  
active ingredient in  
Aleve® Headache Pain  
Tablets

**NAPROXEN**

# HEADACHE PAIN

NAPROXEN SODIUM  
TABLETS, 220 mg

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

For temporary relief of minor headache pain

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®  
Headache Pain Tablets. 50844 REV1221A41716

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

**QUALITY PLUS** NDC 50844-471-16  
Compare to active ingredient in Aleve® Headache Pain Tablets  
**NAPROXEN HEADACHE PAIN**  
**NAPROXEN SODIUM TABLETS, 220 mg**  
PAIN RELIEVER/FEVER REDUCER (NSAID)  
For temporary relief of minor headache pain  
STRENGTH TO LAST 12 HOURS  
1000 Coated Tablets ACTUAL SIZE

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Aleve® Headache Pain Tablets. 50844 REV1221A41716  
Distributed by: **LNK INTERNATIONAL, INC.**  
60 Arkay Drive, Hauppauge, NY 11788  
USA

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

**Drug Facts**

**Active ingredient (in each tablet)**  
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) ..... Pain reliever/fever reducer  
nonsteroidal anti-inflammatory drug

**Uses**  
Temporarily relieves minor aches and pains due to:  
headache musculoskeletal aches minor pain of arthritis toothache the common cold menstrual cramps  
Temporarily reduces fever

**Warnings**  
Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
hives, rash, hives, skin redness, 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 had stomach ulcers or bleeding problems  
take aspirin or for a longer time than directed  
take a blood thinning (anticoagulant) or steroid drug  
use other drugs containing prescription or nonprescription (aspirin, ibuprofen, naproxen, or others)  
Heart attack and stroke warnings: NSAIDs, except aspirin, may 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**  
you are taking a diuretic  
you have a history of stomach problems, such as heartburn  
you have high blood pressure, heart disease, liver disease, 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:  
black, tarry stools  
blood in your stool  
you have symptoms of heart problems or stroke:  
weakness in one part of side of body  
leg swelling  
chest pain  
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 at 20 weeks or later in pregnancy unless specifically 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 4 tablets in any 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 1-800-426-9291 8:30 AM-4:00 PM ET, Monday-Friday

Quality Plus 44-417 HP

## NAPROXEN HEADACHE PAIN

naproxen sodium tablet, film coated

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50844-471

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	ROUND	Size	10mm
Flavor		Imprint Code	44;417
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-471-22	48 in 1 CARTON	09/16/2020	
1	NDC:50844-471-43	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:50844-471-11	60 in 1 CARTON	09/16/2020	
2	NDC:50844-471-43	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:50844-471-99	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	
4	NDC:50844-471-98	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	
5	NDC:50844-471-19	1 in 1 CARTON	09/16/2020	
5		8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:50844-471-56	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	
7	NDC:50844-471-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	

<b>8</b>	NDC:50844-471-16	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204872	09/16/2020	

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(50844-471)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(50844-471)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(50844-471)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(50844-471)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(50844-471)

Revised: 6/2025

L.N.K. International, Inc.