

NAPROXEN SODIUM (NSAID) FEVER REDUCER/ PAIN RELIEVER- naproxen sodium tablet

Amneal Pharmaceuticals of New York LLC

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

Compared to the active ingredient of Aleve® †

Drug Facts

**ACTIVE INGREDIENT
(in each tablet)**

Naproxen sodium USP, 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

INDICATION AND USAGE

Uses

- temporarily relieves minor aches and pains due to:
- backache
- muscular aches
- minor pain of arthritis
- menstrual cramps
- headache
- toothache
- 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:

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

- rash
- blisters

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)
- 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: NSAID, 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 DOCTOR/PHARMACIST

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

WHEN USING

When using this product

- take with food or milk if stomach upset occurs

STOP USE

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:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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

PREGNANCY OR BREAST FEEDING

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

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 to 25°C (68 to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

INACTIVE INGREDIENT

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

Questions or Comments?

Call 1-877-835-5472

Monday through Friday 9 AM – 5 PM EST.

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

†This product is not manufactured or distributed by Bayer Healthcare, LLC., distributor of Aleve®

Rev. 05-2022-03

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 53746-191-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Tablets

Amneal Pharmaceuticals LLC

Exp. Date:
Lot No.:
3
N
53746
19124
3



NDC 53746-191-24

Naproxen Sodium Tablets, USP (NSAID)

220 mg

PAIN RELIEVER/
FEVER REDUCER

13
24 Tablets

Compare to the active ingredient in Aleve®¹

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

Drug Facts (continued)
Inactive ingredients
croscarmellose sodium, FD&C Blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc and titanium dioxide

Questions or Comments?
Call 1-877-835-5472
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Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

¹This product is not manufactured or distributed by Bayer Healthcare, LLC, distributor of Aleve®
Rev. 05-2022-03

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium for 6 weeks or later in pregnancy unless clearly 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
- 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 to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

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 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 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:
- heart burn
- vomit bloody or black stools
- your stomach pain does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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

Important: Read all product information before using.

Drug Facts

Active ingredient
(in each tablet)
Naproxen sodium USP, 220 mg
(naproxen 220 mg) (NSAID)
nonsteroidal anti-inflammatory drug

Purposes
- Pain relief/
fever reducer
(nonsteroidal anti-inflammatory drug)

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - muscular aches
 - minor pain of arthritis
 - menstrual cramps
 - headache
 - toothache
 - 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:

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

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)
- 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: NSAID, 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.

NDC 53746-192-24
Naproxen Sodium Tablets USP (NSAID), 220 mg
24 Caplets
Amneal Pharmaceuticals LLC

Exp. Date:

Lot No.:



NDC 53746-192-24

Naproxen Sodium Tablets, USP (NSAID)

220 mg

PAIN RELIEVER/
FEVER REDUCER

(Capsule-shaped Tablets)
24 Caplets

Compare to the active
ingredient in Aleve®†

DO NOT USE IF PRINTED FOIL UNDER
CAP IS BROKEN OR MISSING

Drug Facts (continued)

Inactive ingredients

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

Questions or Comments?

Call 1-877-835-5472
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Bridgewater, NJ 08807

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Bayer Healthcare, LLC, distributor of Aleve®

Rev. 05-2022-03

17

Drug Facts (continued)

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 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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

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 or 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 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 persistent pain that does not get better
■ you have symptoms of heart problems or stroke:
■ chest pain
■ trouble breathing
■ weakness in one part or side of body
■ slurred speech
■ leg swelling
■ 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

Important: Read all product information before using

Drug Facts

Active ingredient

(in each caplet)
Naproxen sodium USP, 220 mg
(naproxen 220 mg) (NSAID),
nonsteroidal anti-inflammatory drug

Purposes

...Pain reliever/
Fever reducer
nonsteroidal anti-inflammatory drug

Uses

■ Temporarily relieves minor aches and pains due to:
■ backache ■ muscular aches ■ minor pain of arthritis ■ menstrual cramps ■ headache
■ toothache ■ 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:
■ hives ■ skin redness/itching ■ rash ■ blisters
■ asthma (wheezing) ■ shock
■ facial swelling
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) ■ 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: NSAID, 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.

NDC 53746-191-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Tablets

Amneal Pharmaceuticals LLC

NDC 53746-191-24

Naproxen Sodium Tablets, USP (NSAID)

220 mg

Pain reliever /
Fever reducer



24 Tablets

13

Drug Facts

Active ingredient

(in each tablet)
Naproxen sodium USP, 220 mg ...Pain reliever/
(naproxen 200 mg) (NSAID)*
* nonsteroidal anti-inflammatory drug

Purposes

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

Uses

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

Do not use if imprinted foil inner seal on bottle is broken or missing.

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Bridgewater, NJ 08807

Mfg. Lic. No. G/29/12271

Rev. 05-2022-03



Lot No:

Non-Varnish Area

Exp. Date:

Drug Facts (continued)

Warnings

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

- hives
 - asthma (wheezing)
 - skin reddening
 - facial swelling
 - shock
 - rash
 - blisters
- 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) ■ 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: NSAID, 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 are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Drug Facts (continued)

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:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
 - 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 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.

Drug Facts (continued)

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

Other information

- each tablet contains: sodium 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

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

Questions or Comments?

Call 1-877-835-5472
Monday through Friday 9AM - 5PM EST.

**PERMANENT
GLUE**

PEEL BACK FOR ADDITIONAL DRUG FACTS

PEEL BACK FOR ADDITIONAL DRUG FACTS

PEEL BACK FOR ADDITIONAL DRUG FACTS

NDC 53746-192-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Caplets

Amneal Pharmaceuticals LLC

NDC 53746-192-24

Naproxen Sodium Tablets, USP (NSAID)

220 mg

Pain reliever/
Fever reducer

(Capsule-shaped Tablets)
24 Caplets



17

Drug Facts

Active ingredient (in each caplet)

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

Uses

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

Do not use if imprinted foil inner seal on bottle is broken or missing.

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Bridgewater, NJ 08807

Mfg. Lic. No. G/29/12271

Rev. 05-2022-03



N 3 53746 19224 0

Lot No:

Non-Varnish Area

Exp. Date:

Drug Facts (continued)

Warnings

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

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

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

Drug Facts (continued)

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:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
 - 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 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.

Drug Facts (continued)

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
- ask a doctor

Children under 12 years

Other information

- each caplet contains: sodium 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

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

Questions or Comments?

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Monday through Friday 9AM - 5 PM EST.

**PERMANENT
GLUE**

PEEL BACK FOR ADDITIONAL DRUG FACTS

PEEL BACK FOR ADDITIONAL DRUG FACTS

PEEL BACK FOR ADDITIONAL DRUG FACTS

NDC 53746-191-08

Naproxen Sodium Tablets USP (NSAID), 220 mg

8 Tablets

Amneal Pharmaceuticals LLC

amneal® NDC 53746-191-08
**Naproxen Sodium
Tablets, USP (NSAID)**
220 mg 13
Compare to the active ingredient of Aleve® †
DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING PAIN RELIEVER/FEVER REDUCER 8 Tablets

READ VIAL BLISTER CARD FOR COMPLETE PRODUCT INFORMATION.

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

Purposes
Pain reliever/fever reducer

Uses: ■ temporarily relieves minor aches and pains due to: ■ backache ■ muscular aches ■ minor pain of arthritis ■ menstrual cramps ■ headache ■ toothache ■ the common cold ■ temporarily reduces fever **Warnings: 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, rofecoxib, 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:** NSAID, 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.

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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Questions or Comments? Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST.
Distributed by: Amneal Pharmaceuticals LLC - Bridgewater, NJ 08807 Rev. 11-2017-01

Lot No.
Exp. Date:

Purse Pack

NDC 53746-192-08

Naproxen Sodium Tablets USP (NSAID), 220 mg

8 Caplets

Amneal Pharmaceuticals LLC

 NDC 53746-192-08

Naproxen Sodium Tablets, USP (NSAID)

220 mg 17

Compare to the active ingredient of Aleve® †

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

PAIN RELIEVER/FEVER REDUCER *Capsule-shaped Tablets

READ VIAL BLISTER CARD FOR COMPLETE PRODUCT INFORMATION.

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

Purposes
Pain reliever/fever reducer

Uses: ■ temporarily relieves minor aches and pains due to: ■ backache ■ muscular aches ■ minor pain of arthritis ■ menstrual cramps ■ headache ■ toothache ■ the common cold ■ temporarily reduces fever **Warnings: 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) ■ 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:** NSAID, 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.

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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Questions or Comments? Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST.
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Lot No.
Exp. Date:

Purse Pack

NDC 53746-191-16

Naproxen Sodium Tablets USP (NSAID), 220 mg

16 Tablets

Amneal Pharmaceuticals LLC

 NDC 53746-191-16



Naproxen Sodium Tablets, USP (NSAID)

220 mg 13

TAMPER EVIDENT:
Use Only if Blister is Intact

Compare to the active ingredient of Aleve® †

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

PAIN RELIEVER/
FEVER REDUCER 16 Tablets
(2 vials - 8 tablets each)

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: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ 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 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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

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

Questions or Comments? Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST.

*This product is not manufactured or distributed by the Bayer Corporation, Consumer Care Division, distributor of ALEVE® Tablets.

†ALEVE® is a registered trademark of Bayer-Roche L.L.C.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 05-2022-03

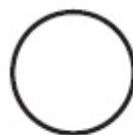
Purse Pack

NDC 53746-192-16

Naproxen Sodium Tablets USP (NSAID), 220 mg

16 Caplets

Amneal Pharmaceuticals LLC



NDC 53746-**192**-16

**Naproxen Sodium
Tablets, USP (NSAID)**

220 mg

TAMPER EVIDENT:
Use Only if Blister is Intact

Compare to the active
ingredient of Aleve®†

17

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) ■ 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: NSAID, 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 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 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: ■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling ■ 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 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 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° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

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

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Bridgewater, NJ 08807

Rev. 05-2022-03

NAPROXEN SODIUM (NSAID) FEVER REDUCER/ PAIN RELIEVER

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53746-191
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		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
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 (Biconvex)	Size	10mm	
Flavor		Imprint Code	I3	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53746-191-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	
2	NDC:53746-191-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	
3	NDC:53746-191-08	8 in 1 VIAL; Type 0: Not a Combination Product	11/25/2009	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA079096	11/25/2009		

NAPROXEN SODIUM (NSAID) FEVER REDUCER/ PAIN RELIEVER

naproxen sodium tablet

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Route of Administration	ORAL		

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Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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	OVAL (Biconvex)	Size	12mm
Flavor		Imprint Code	I7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53746-192-08	8 in 1 VIAL; Type 0: Not a Combination Product	11/25/2009	
2	NDC:53746-192-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	
3	NDC:53746-192-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	11/25/2009	

Labeler - Amneal Pharmaceuticals of New York LLC (123797875)