

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 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 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

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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. 11-2017-01

PACKAGE LABEL/PRINCIPAL DISPLAY PANEL

NDC 53746-191-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Tablets

Amneal Pharmaceuticals

1 1/2"

1 1/2"

Exp. Date: _____
Lot No.: _____

3 53746 19124 3 N

Important: Read all product information before using.

Drug Facts
Active ingredient (in each tablet)
Naproxen sodium USP, 220 mg (naproxen 200 mg) (NSAID)[†]
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
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 ■ blisters
skin reddening ■ rash

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.

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 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
lag 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

Drug Facts (continued)

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 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).

Amneal

Compare to the active ingredient in Aleve®†

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

220 mg

Naproxen Sodium Tablets, USP (NSAID)

**PAIN RELIEVER/
FEVER REDUCER**

24 Tablets

NDC 53746-191-24

Drug Facts (continued)

Inactive ingredients
croscarmellose sodium, FD&C Blue #2, maroon, magnesium stearate, polyvinyl alcohol, polydioxane, pregelatinized starch, talc, and titanium dioxide

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

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

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

Rev. 11-2017-01

NDC 53746-192-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Caplets

Amneal Pharmaceuticals

1 1/2" 2" 1 1/2" 2"

Exp. Date: Lot No. 3Z 53746 19224 0

Important: Read all product information before using.

Drug Facts

Active ingredient (in each caplet)
Naproxen sodium USP, 220 mg (naproxen 200 mg) (NSAID)*
*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
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 ■ blisters
■ skin reddening ■ rash ■ rash
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.

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 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

Drug Facts (continued)

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 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).

Compare to the active ingredient in Aleve®
DO NOT USE IF PRINTED FOR UNDER CAP IS BROKEN OR MISSING

amneal

220 mg

**PAIN RELIEVER/
FEVER REDUCER**

**(Capsule-shaped Tablets)
24 Caplets**

NDC 53746-192-24

17

Drug Facts (continued)

Inactive ingredients
D-oxycarmellose sodium, FD&C Blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, 1,3-cis and trans-butyl diols

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

Distributed by: Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807
*This product is not manufactured or distributed by Bayer Healthcare, LLC, distributor of Aleve®
Rev. 11-2017-01

NDC 53746-191-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Tablets

Amneal Pharmaceuticals

NDC 53746-191-24

220 mg

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

Pain reliever /
Fever reducer

24 Tablets

13

amneal

Drug Facts

Active ingredient (in each tablet)	Purposes
Naproxen sodium USP, 220 mg (naproxen 200 mg) (NSAID)*	...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

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

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

Mfg. Lic. No. G/29/12271
Rev. 11-2017-01

N 3 53746 19124 3

Lot No: _____

Exp. Date: _____

Non-Varnish Area

PEEL BACK FOR ADDITIONAL DRUG FACTS

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
- 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

PEEL BACK FOR ADDITIONAL DRUG FACTS

Drug Facts (continued)

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:
 - 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 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 right away.

PEEL BACK FOR ADDITIONAL DRUG FACTS

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

<p>Adults and children 12 years and older</p>	<ul style="list-style-type: none"> ■ 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
<p>Children under 12 years</p>	<ul style="list-style-type: none"> ■ 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.

PERMANENT
GLUE

NDC 53746-192-24

Naproxen Sodium Tablets USP (NSAID), 220 mg

24 Caplets

Amneal Pharmaceuticals

NDC 53746-192-24

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

220 mg

Pain reliever/
Fever reducer

(Copyrighted Tablets)
24 Caplets

amneal

17

Drug Facts	
Active ingredient (in each caplet) Naproxen sodium USP, 220 mg ...Pain reliever/ (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug	Purposes ...Pain reliever/ fever reducer
Uses <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ 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. Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 Mfg. Lic. No. G/29/12271 Rev. 11-2017-01	
	
Lot No:	Non-Varnish Area
Exp. Date:	

PEEL BACK FOR ADDITIONAL DRUG FACTS

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 ■ 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

PEEL BACK FOR ADDITIONAL DRUG FACTS

Drug Facts (continued)

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:
 ■ 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 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 right away.

PEEL BACK FOR ADDITIONAL DRUG FACTS

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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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

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

PERMANENT GLUE

Purse Pack

NDC 53746-191-08

Naproxen Sodium Tablets USP (NSAID), 220 mg

8 Tablets

Amneal Pharmaceuticals



NDC 53746-191-08

Naproxen Sodium Tablets, USP (NSAID)

Compare to the active
ingredient of Aleve®†

220 mg

13

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

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 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



NDC 53746-192-08

Naproxen Sodium Tablets, USP (NSAID)

Compare to the active
ingredient of Aleve®†

220 mg

17

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

PAIN RELIEVER/FEVER REDUCER

8 Caplets*

*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

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.

Distributed by: Amneal Pharmaceuticals LLC - Bridgewater, NJ 08807

Rev. 11-2017-01

Lot No.

Exp. Date:

Purse Pack

NDC 53746-191-16

Naproxen Sodium Tablets USP (NSAID), 220 mg

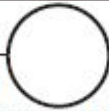
16 Tablets

Amneal Pharmaceuticals

Drug Facts

Active ingredient (in each tablet)

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



Purposes

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 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 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 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 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. 11-2017-01

Purse Pack

NDC 53746-192-16

Naproxen Sodium Tablets USP (NSAID), 220 mg

16 Caplets

Amneal Pharmaceuticals

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium USP, 220 mg
(naproxen 200 mg) (NSAID)*



*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

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 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 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 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 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

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

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Distributed by: Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 11-2017-01

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:53746-191-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	
2	NDC:53746-191-08	8 in 1 VIAL; Type 0: Not a Combination Product	11/25/2009	
3	NDC:53746-191-24	24 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	

NAPROXEN SODIUM (NSAID) FEVER REDUCER/ PAIN RELIEVER

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53746-192
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)	
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:53746-192-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/25/2009	
2	NDC:53746-192-08	8 in 1 VIAL; Type 0: Not a Combination Product	11/25/2009	
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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)