

**GOOD SENSE NAPROXEN SODIUM- naproxen sodium tablet, film coated
Proficient Rx LP**

Perrigo Naproxen Sodium Tablets, 220 mg Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg
(naproxen 200 mg) (NSAID)*
*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- minor pain of arthritis
- muscular aches
- backache
- 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

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

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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
 - 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. (1-800-222-1222)

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 21 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Strength To Last 12 Hours

Naproxen Sodium Tablets, 220 mg

Actual Size

Pain Reliever & Fever Reducer (NSAID)

Compare to active ingredient of Aleve® Caplets

20 Caplets†

†Capsule-Shaped Tablets



NDC 63187-794-20

Lot #:00000
Exp. 00/00/00
SN# MASTER

Naproxen Sodium 220mg

#20 Tablets

Each tablet contains: Naproxen sodium 220 mg
(naproxen 200 mg)(NSAID)* Pain reliever/ fever
reducer *nonsteroidal anti-inflammatory drug

Blue (Light Blue), capsule (oval) shaped, unscored tablet with imprint code "L368"

Product ID: PN079420

Dist. By: Perrigo Allegan, MI 49010

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Naproxen Sodium 220mg
#20 Tablets
Lot #:00000 Rx# MASTER
NDC 63187-794-20 Exp:00/00/00

Naproxen Sodium 220mg
#20 Tablets
Lot #:00000 Rx# MASTER
NDC 63187-794-20 Exp:00/00/00

Naproxen Sodium 220mg
#20 Tablets
Lot #:00000 Rx# MASTER
NDC 63187-794-20 Exp:00/00/00

Packaged By: Proficient Rx LP
Thousand Oaks, CA 91320



EXP. : 36 852 22 12

EXP.

LOT NO.

3 N 0113-4368-62 3



Drug Facts

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

Uses ■ temporarily relieves minor aches and pains due to:
■ minor pain of arthritis ■ muscular aches ■ backache
■ 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

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, or kidney disease ■ you are taking a diuretic ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have asthma ▶

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 ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 ■ 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. (1-800-222-1222)

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Adults and children 12 years and older:
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■ 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 21 mg ■ store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). ▼

Drug Facts (continued)

Inactive ingredients: FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide
Questions or comments? 1-800-719-9290

Gluten Free

Distributed By

Perigo®

Allegan, MI 49010

GOOD SENSE NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-794(NDC:0113-4368)
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (Light Blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	L368
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-794-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2016	
2	NDC:63187-794-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2016	
3	NDC:63187-794-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	03/31/2014	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-794)

Revised: 11/2019

Proficient Rx LP