

EQUALINE NAPROXEN SODIUM- naproxen sodium tablet, film coated
Supervalu Inc

SuperValu Inc. Naproxen Sodium Tablets 220mg 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

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you 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 (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?

1-877-932-7948

Principal Display Panel

compare to Aleve® active ingredient

naproxen sodium tablets 220mg

pain reliever/ fever reducer (NSAID)

strength to last 12 hours

SEE NEW WARNINGS
 50 caplets**
 **capsule-shaped tablets
 actual size

Drug Facts

Active ingredient (in each caplet):
 naproxen sodium 220 mg
 (naproxen 200 mg (NSAID))

Purposes:
 Pain reliever
 Fever reducer

Uses: Temporary relief from achy and painful joints
 Minor pain of arthritis
 Muscular aches
 Headaches
 Menstrual cramps
 Headaches
 Toothaches
 Common cold
 Temporary relief from fever

Warnings:
 Allergy alert: Naproxen sodium may cause an allergic-type reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma, wheezing, shock, skin redness, rash, itching. 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 in the past; take other drugs containing aspirin, aspirin, or other NSAIDs (ibuprofen, naproxen, or others); have 3 or more alcoholic drinks a day while using this product; take more or for a longer time than directed.
 Heart disease 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: You do much bleeding, warning applies to you; you have a history of stomach problems, such as heartburn; you have high blood pressure, heart disease, liver or kidney, kidney disease, asthma, or had a stroke; you are taking other drugs.

Drug Facts (continued)

If you have problems or serious side effects from using pain relievers or fever reducers:
 Ask a doctor or pharmacist before use if you are: Working a doctor's care for any condition; taking any other drug; pregnant or breastfeeding; taking with food or milk; a stomach upset occurs.

Stop use and ask a doctor if: you experience any of the following: sharp stomach bleeding; feel faint; worried about dizziness or lightheadedness; have sharp pain that doesn't get better; you have symptoms of heart problems or stroke; chest pain; trouble breathing; weakness in one part or side of body; dizziness; ringing in ears; you get worse or feel more than 10 days; have redness, swelling, or itching on the face, lips, or mouth; you have difficulty swallowing; it feels like the pill is sticking in your throat; redness or swelling in the eyes; any new symptoms appear.

If pregnant or breast-feeding, ask a health professional before use. Use only if your doctor says you should use it. Do not use for the last 3 months of pregnancy unless specifically directed to do so by a doctor, because they can 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 with or without food.
 Do not exceed 2 caplets in any 12-hour period.
 Children under 12 years: Ask a doctor.

Other information: Each caplet contains the sodium, 21 mg (sodium chloride, 55.3 mg). Avoid high in salt and excessive heat above 40°C (104°F).

KEEP CARTON FOR REFERENCE



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GLUTEN FREE

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Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Do not use for the last 3 months of pregnancy unless specifically directed to do so by a doctor, because they can 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).

Other information: Each caplet contains the sodium, 21 mg (sodium chloride, 55.3 mg). Avoid high in salt and excessive heat above 40°C (104°F).



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

Actual Size

EQUALINE®

compare to Aleve® active ingredient***
 NDC 41163-511-71

naproxen sodium
 tablets 220mg
 pain reliever/fever reducer (NSAID)
 strength to last 12 hours

SEE NEW WARNINGS

50 caplets** *capsule-shaped tablets

actual size



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-511
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (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:41163-511-71	1 in 1 CARTON	09/24/2014	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41163-511-62	1 in 1 CARTON	09/24/2014	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41163-511-78	1 in 1 CARTON	09/24/2014	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	09/24/2014	

Labeler - Supervalu Inc (006961411)

