

ALL DAY PAIN RELIEF- naproxen sodium tablet
Rebel Distributors Corp

All Day Pain Relief Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- 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 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
 - you develop heartburn
 - 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
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

Adults and children 12	<ul style="list-style-type: none">• take 1 tablet every 8 to 12 hours while symptoms last
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years and older	<ul style="list-style-type: none"> • 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 20-25°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

See New Warnings Information

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever & Fever Reducer (NSAID)

Actual Size

Compare to active ingredient of Aleve® Tablets

Peel

Naproxen Sodium 220mg
#30 Tablets Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-230-30 AWP: \$19.43



NDC 42254-230-30

Naproxen Sodium 220mg

#30 Tablets

Each tablet contains: Naproxen sodium 220mg Pain Reliever/ Fever Reducer (Naproxen 200mg) (NSAID)

Light blue, round tablets, biconvex, debossed with "L490" on one side and plain on the other side.

Lot #: 000000

Exp. 00/00/00

030320N0

Product ID: QN023030

RX#Master Dist. By: Perrigo, Allegan, MI 49010

Peel

Naproxen Sodium 220mg
#30 Tablets Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-230-30 AWP: \$19.43

Packaged by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
 Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

ALL DAY PAIN RELIEF

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-230(NDC:0 113-9490)
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	ROUND	Size	10mm
Flavor		Imprint Code	L490
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-230-14	14 in 1 BOTTLE		
2	NDC:42254-230-20	20 in 1 BOTTLE		
3	NDC:42254-230-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	01/14/1997	

Labeler - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-230)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-230)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-230) , REPACK(42254-230)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-230) , REPACK(42254-230)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-230)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-230) , REPACK(42254-230)

Revised: 5/2012

Rebel Distributors Corp