ALL DAY PAIN RELIEF- naproxen sodium tablets, 220 mg tablet
We Care Distributor Inc.

All Day Pain Relief - Naproxen Sodium Tablets, 220 mg

Drug Facts

Active ingredients (in each tablet)	*Purposes*
Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)*	Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug	

* *

Uses

■ temporarily relieves minor aches and pains due to:

■ minor pain of arthritis ■ muscular aches ■ backache ■ headache

■ menstrual cramps ■ 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

■ 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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

■ take 1 tablet every 8 to 12 hours while symptoms last 12 years and older

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

Inactive ingredients

FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

Compare to the Active Ingredients in Aleve®.

ALL DAY PAIN RELIEF

Naproxen Sodium Tablets, 220 mg

TO OPEN
PUSH IN TAB AND PULL OUT

25 Pouches of 2 Caplets Each

ALL DAY PAIN RELIEF

naproxen sodium tablets, 220 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70005-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	220 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE (Light Blue)	**Score**	no score
Shape	OVAL (Capsule-Shaped)	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-008-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-008-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-008-02	2 in 1 POUCH		
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	09/30/2011	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-008)

Revised: 2/2016 We Care Distributor Inc.