**ALL DAY PAIN RELIEF- naproxen sodium tablets, 220 mg tablet**
**HealthLife of USA LLC**

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**All Day Pain Relief - Naproxen Sodium Tablets, 220 mg**

***Drug Facts***

**Active ingredient (in each caplet)** **Purpose**

Naproxen Sodium 220 mg

(naproxen 200mg) (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

**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 (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 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 20-25° C (68-77° F).

■ avoid high humidity and excessive heat above 40° C (104° F)

■ read all product information before using

**■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

**Questions or comments?**

Call toll free 1-844-832-1138 Monday through Friday 9AM – 5PM EST or www.healthlifeofusa.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***


**ALL DAY PAIN RELIEF**

naproxen sodium tablets, 220 mg tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69517-109 |
| **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:69517-109-25 | 25 in 1 BOX | 04/07/2016 | |
| **1** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| **2** | NDC:69517-109-50 | 50 in 1 BOX | 04/07/2016 | |
| **2** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| **3** | NDC:69517-109-02 | 2 in 1 POUCH | 04/07/2016 | |
| **3** | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| **4** | NDC:69517-109-04 | 400 in 1 BOTTLE | 04/07/2016 | |
| **4** | NDC:69517-109-01 | 100 in 1 BOTTLE | | |
| **4** | NDC:69517-109-24 | 24 in 1 BOTTLE | | |
| **4** | | 1 in 1 CARTON; 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 - HealthLife of USA LLC (079656178)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Granules India Limited | | 918609236 | manufacture(69517-109) |

Revised: 6/2017 HealthLife of USA LLC