**ALL DAY RELIEF - naproxen sodium tablet**
**H.J. Harkins Company, Inc.**

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**Major Pharmaceuticals All Day 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 | • 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<br>• do not exceed 2 tablets in any 8- to 12-hour period<br>• 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 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**

Compare to the active ingredient of Aleve® Tablets

See New Warnings Information

All Day Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever, Fever Reducer (NSAID)

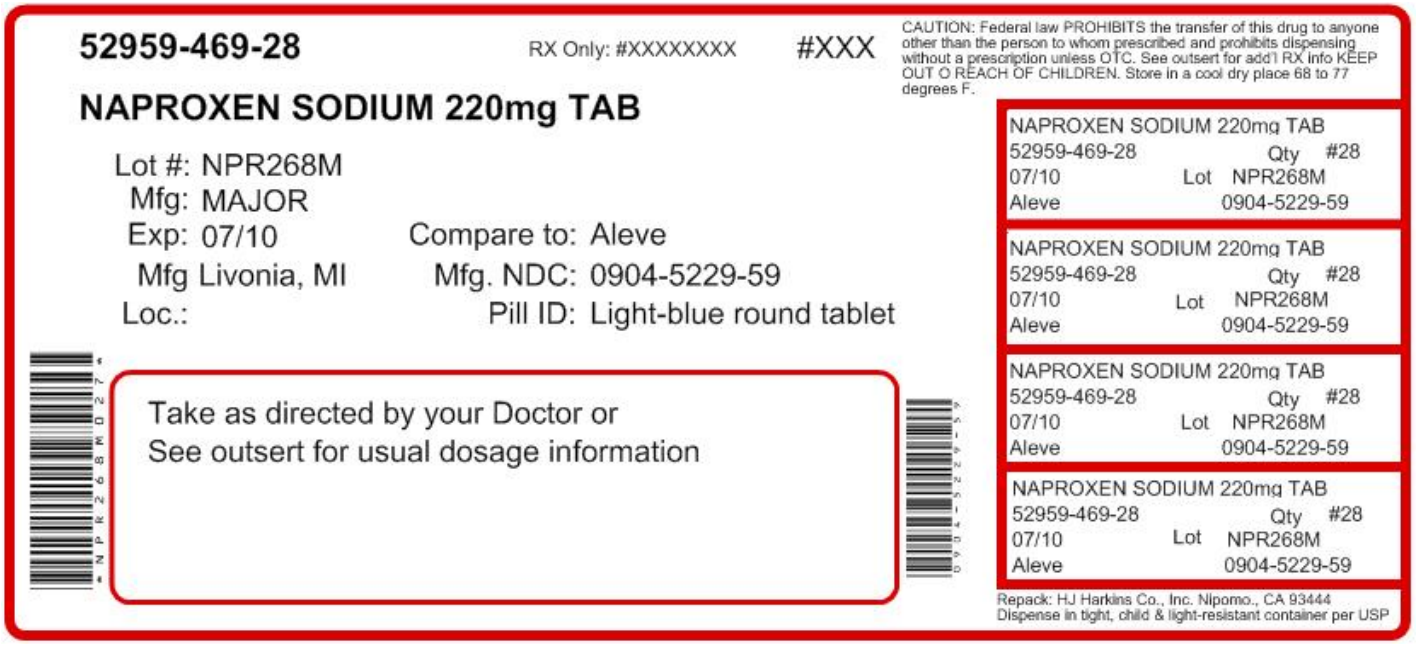
Strength to Last 12 Hours

Actual Size

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444




**All Day Relief Carton Image 1**

# ALL DAY RELIEF

naproxen sodium tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:52959-469(NDC:0904-5229) |
| **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 GLYCOL** (UNII: 3WJQ0SDW1A) | |
| **POVIDONE** (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:52959-469-15 | 15 in 1 BOTTLE | | |
| 2 | NDC:52959-469-20 | 20 in 1 BOTTLE | | |
| 3 | NDC:52959-469-24 | 24 in 1 BOTTLE | | |
| 4 | NDC:52959-469-28 | 28 in 1 BOTTLE | | |
| 5 | NDC:52959-469-30 | 30 in 1 BOTTLE | | |
| 6 | NDC:52959-469-40 | 40 in 1 BOTTLE | | |
| 7 | NDC:52959-469-60 | 60 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA074661 | 01/09/1997 | |

## Labeler - H.J. Harkins Company, Inc. (147681894)

## Registrant - H.J. Harkins Company, Inc. (147681894)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| H.J. Harkins Company, Inc. | | 147681894 | relabel, repack |

Revised: 2/2012 H.J. Harkins Company, Inc.