# ASPIRIN LOW DOSE CHEWABLE- aspirin tablet, chewable Time-Cap Labs, Inc

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#### Aspirin 81 mg Low Dose Chewable Tablets Orange Flavor

### **ACTIVE INGREDIENTS**

Active ingredient (in each tablet) Purpose

Aspirin 81 mg (NSAID\*).....Pain reliever

\*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever

#### Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor
- ask your doctor about other uses for 81 mg orange chewable aspirin

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**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 are allergic to aspirin or any other pain reliever/fever reducer
- this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor
- if you have ever had an allergic reaction to this product or any of its ingredients

# Ask a doctor before use if

- 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 taking a prescription drug for

- gout
- diabetes
- arthritis

### Stop use and ask a doctor if

an allergic reaction occurs. Seek medical help right away.

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 redness or swelling is present new symptoms occur ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin 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.

# Other information

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

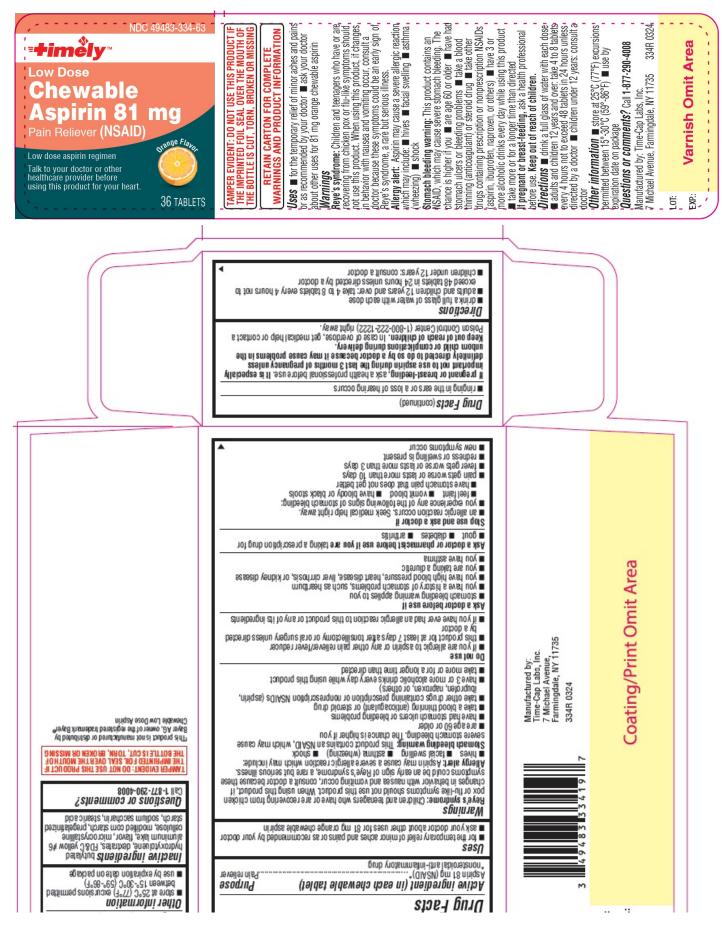
# Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

*Inactive ingredients* butylated hydroxytoluene, dextrates, FD&C yellow #6 aluminum

lake, flavor, microcrystalline cellulose, modified corn starch, pregelatinized starch, sodium saccharin, stearic acid

#### Questions or comments? Call 1-877-290-4008





# **ASPIRIN LOW DOSE CHEWABLE**

aspirin tablet, chewable

| Product Information     |                |                    |               |  |  |  |
|-------------------------|----------------|--------------------|---------------|--|--|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49483-334 |  |  |  |
| Route of Administration | ORAL           |                    |               |  |  |  |

| Active Ing                    | redient/Active           | e Moiety   |            |                         |                       |  |
|-------------------------------|--------------------------|--|------------|-------------------------|-----------------------|--|
|                               | Ingredient Name          |  |            | Basis of Streng         | th Strength           |  |
| ASPIRIN (UNII:                | R16CO5Y76E) (AS          | PIRIN - UNII:R16C05Y76E)                                   |            | ASPIRIN                 | 81 mg                 |  |
|                               |                          |  |            |                         |                       |  |
| Inactive Ir                   | gredients                |  |            |                         |                       |  |
|                               |                          | Ingredient Name  |            |                         | Strength              |  |
| BUTYLATED H                   | IYDROXYTOLUEN            | E (UNII: 1P9D0Z171K)                                       |            |                         |                       |  |
| DEXTRATES (                   | JNII: G263MI44RU)        |  |            |                         |                       |  |
| FD&C YELLO                    | <b>N NO. 6</b> (UNII: H7 | 7VEI93A8)  |            |                         |                       |  |
| CELLULOSE,                    | MICROCRYSTALL            | INE (UNII: OP1R32D61U)                                     |            |                         |                       |  |
| MODIFIED CO                   | RN STARCH (1-0           | CTENYL SUCCINIC ANHYDRI                                    | DE) (UNII: | 461P5CJN6T)             |                       |  |
| ORANGE (UNII                  | : 5EVU04N5QU)            |  |            |                         |                       |  |
| STARCH, COP                   | <b>N</b> (UNII: 08232NY3 | 3SJ)   |            |                         |                       |  |
| SACCHARIN S                   | ODIUM (UNII: SB8         | ZUX40TY)   |            |                         |                       |  |
| STEARIC ACIE                  | ) (UNII: 4ELV7Z65A       | P)   |            |                         |                       |  |
|                               |                          |  |            |                         |                       |  |
| Product C                     | haracteristics           | 5  |            |                         |                       |  |
| Color                         | orange                   | Score  | no so      | core                    |                       |  |
| Shape                         | ROUND                    | Size   | 8mm        |                         |                       |  |
| Flavor                        |                          | Imprint Code   | UPPE       | R;tcl334;LOWER;PLAIN    |                       |  |
| Contains                      |                          |  |            |                         |                       |  |
|                               |                          |  |            |                         |                       |  |
| Packaging                     |                          |  |            |                         |                       |  |
| # Item Co                     | de F                     | Package Description  |            | Marketing Start<br>Date | Marketing End<br>Date |  |
| <b>1</b> NDC:49483-<br>334-63 |                          | 36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |            | 2/17/2018               |                       |  |
| <b>2</b> NDC:49483-<br>334-00 | 100000 in 1 0<br>Product | 100000 in 1 CARTON; Type 0: Not a Combination Product      |            | 2/17/2018               |                       |  |
| <b>3</b> NDC:49483-334-19     | 3 in 1 CARTO             | 3 in 1 CARTON  |            | 4/19/2024               |                       |  |
| 3                             | 36 in 1 BOTT             | 36 in 1 BOTTLE; Type 0: Not a Combination Product          |            |                         |                       |  |
|                               |                          |  |            |                         |                       |  |
| Markoti                       | ng Informa               | tion   |            |                         |                       |  |
| IGINELI                       | -                        | ation Number or Monogra                                    | aph        | Marketing Start         | Marketing End         |  |
| Marketi                       |                          | Citation   | •          | Date                    | Date                  |  |
|                               | ry                       |  | -          |                         |                       |  |

Labeler - Time-Cap Labs, Inc (037052099)

Registrant - Time-Cap Labs, Inc (037052099)

| Establishment      |         |           |                            |  |  |  |
|--------------------|---------|-----------|----------------------------|--|--|--|
| Name               | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |
| Time-Cap Labs, Inc |         | 037052099 | manufacture(49483-334)     |  |  |  |

Revised: 4/2024

Time-Cap Labs, Inc