ASPIRIN- aspirin tablet 325mg tablet WinCo Foods LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

011R Winco Foods 67091 382 Aspirin tablet 325mg 100 ct and 300ct

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- for the temporary relief of minor aches and pains due to
- o headache
- o colds
- o muscle pain
- o menstrual pain
- o toothache
- o minor pain of arthritis
- temporarily reduces fever

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
- shock
- asthma (wheezing)

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 to Aspirin or any other pain reliever/fever reducer

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
- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- o feel faint
- o have bloody or black stools
- o vomit blood
- o 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 in the painful area
- any new symptoms appear
- 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 right away.

Directions

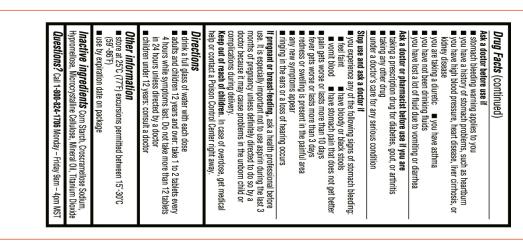
- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours while symptoms last. Do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

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

Inactive ingredients corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

Questions? Call 1-800-824-1706 Monday - Friday 9am - 4pm MST





■ headache
 ■ colds
 ■ minor pain of arthritis

Active ingredient (in each tablet)

Orug Facts

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 Reye's syndrome: Children and teenagers who have or are facial swelling temporarily reduces fever may include: ■ hives

 * This product is not manufactured or distributed by BAYER HEALTHCARE LLC, distributor of GENUINE BAYER $^{\circ}$ **UNVARNISHED AREA** DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704 J11R 0222 WF2202 LOT NO.: EXP. DATE:

Drug Facts (continued under label)

■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed ■ if you are allergic to aspirin or any other pain reliever/fever reducer

take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

■ have had stomach ulcers or bleeding problems
 ■ take a blood thinning (anticoagulant) or steroid drug

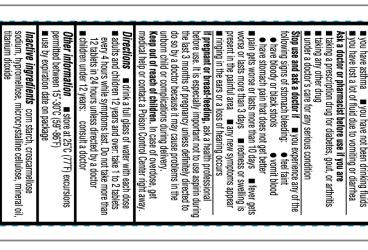
Stomach bleeding warning: This product contains an NSAID, which

asthma (wheezing)

shock

may cause severe stomach bleeding. The chance is higher if you:

are age 60 or older



■ you have high blood pressure, heart disease, liver cirrhosis

or kidney disease

you are taking a diuretic

■ you have a history of stomach problems, such as heartburn

stomach bleeding warning applies to you

Ask a doctor before use if

other pain reliever/fever reducer **Drug Facts** (continued)

Do not use if you have ever had an allergic reaction to any



ASPIRIN

aspirin tablet 325mg tablet

(Juestions? Call **1-800-824-1706** Monday – Friday 9am – 4pm MST

Adhesive Area

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67091-382 | |
| Route of Administration | ORAL | | | |

| Active Ingredient/Active Moiety | | | | |
|--|--------------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | AS PIRIN | 325 mg | | |
| | | | | |

| Inactive Ingredients | |
|----------------------|----------|
| Ingredient Name | Strength |

| STARCH, CORN (UNII: O8232NY3SJ) | |
|--|--|
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48) | |

| Product Characteristics | | | | | |
|-------------------------|-------|--------------|----------|--|--|
| Color | white | Score | no score | | |
| Shape | ROUND | Size | 10mm | | |
| Flavor | | Imprint Code | TCL011 | | |
| Contains | | | | | |

| l | Packaging | | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | NDC:67091-382- 10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/18/2022 | | |
| | 2 | NDC:67091-382- 30 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 01/18/2022 | | |

| Marketing Information | | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part343 | 01/18/2022 | | |
| | | | | |

Labeler - WinCo Foods LLC (056098817)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

| Establishment | | | |
|-----------------------------|---------|-----------|----------------------------|
| Na me | Address | ID/FEI | Business Operations |
| TIME CAP LABORATORIES, INC. | | 037052099 | manufacture(67091-382) |

Revised: 5/2022 WinCo Foods LLC