

**ASPIRIN- aspirin tablet, coated**  
**TIME CAP LABS INC**

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**Aspirin 325 mg tablets**

**DRUG FACTS**

***Active ingredient (in each tablet)***

Aspirin 325 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

**INDICATIONS AND USAGE**

***Uses***

for the temporary relief of minor aches and pains due to

- headache
- colds
- menstrual pain
- muscle pain
- toothache
- minor pain of arthritis

or as directed by your doctor

***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
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs (aspirin,

ibuprofen, naproxen, or others)

### **Do not use**

- if you are 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 asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- 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:

- feel faint
- have bloody or black stools
- vomit blood
- 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

**PRINCIPAL DISPLAY PANEL**

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ have 3 or more alcoholic drinks every day while using this product</li> <li>■ take more or for a longer time than directed</li> </ul> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you are allergic to aspirin or any other pain reliever/fever reducer</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>■ stomach bleeding warning applies to you</li> <li>■ you have a history of stomach problems, such as heartburn</li> <li>■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease</li> <li>■ you are taking a diuretic</li> <li>■ you have asthma</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug for</b></p> <ul style="list-style-type: none"> <li>■ gout</li> <li>■ diabetes</li> <li>■ arthritis</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ an allergic reaction occurs. Seek medical help right away.</li> <li>■ you experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>■ vomit blood</li> <li>■ have bloody or black stools</li> <li>■ have stomach pain that does not get better</li> <li>■ pain gets worse or lasts more than 10 days</li> <li>■ ever gets worse or lasts more than 3 days</li> <li>■ redness or swelling is present</li> </ul> </li> <li>■ new symptoms occur</li> <li>■ ringing in the ears or a loss of hearing occurs</li> </ul> <p><b>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.</b></p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ drink a full glass of water with each dose</li> <li>■ adults and children 12 years and over: take 1 to 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours</li> <li>■ children under 12 years: consult a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)</li> <li>■ use by expiration date on package</li> </ul> <p><b>Inactive ingredients</b> corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide</p> <p><b>Questions or comments? Call 1-877-290-4008</b></p>
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Adhesive Area

Inside

1/16" Margin

<p>NDC 49483-011-31</p> <p><b>timely™</b></p> <p>Regular Strength</p> <p><b>ASPIRIN 325 mg</b></p> <p>Pain Reliever/Fever Reducer (NSAID)</p> <p>For adults Safe pain relief plus lifesaving benefits</p> <p><b>300</b> COATED TABLETS</p> <p>ACTUAL SIZE</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> <i>Purposes</i></p> <p>Aspirin, 325 mg (NSAID)* ..... Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ temporarily relieves minor aches and pains due to:             <ul style="list-style-type: none"> <li>■ headache</li> <li>■ muscle pain</li> <li>■ toothache</li> <li>■ menstrual pain</li> <li>■ colds</li> <li>■ minor pain of arthritis</li> </ul> </li> <li>■ temporarily reduces fever</li> </ul> <p><b>Warnings</b></p> <p><b>Reye's syndrome:</b> 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.</p> <p><b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> <li>■ hives</li> <li>■ facial swelling</li> <li>■ asthma (wheezing)</li> <li>■ shock</li> </ul> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> <li>■ are age 60 or older</li> <li>■ have had stomach ulcers or bleeding problems</li> <li>■ take a blood thinning (anticoagulant) or steroid drug</li> <li>■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> </ul>	<p><b>Drug Facts (continued under label)</b></p> <p>This product is not manufactured or distributed by Bayer Healthcare LLC., distributor of Bayer® Aspirin</p> <p>Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735</p> <p>11R 1123</p> <p>Lot: _____ Exp.: _____</p> <p>3 0 9 4 8 3 1 1 1 3 1 9</p> <p><b>Varnish Omit Area</b></p> <p>PEEL HERE</p>
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P.O. #

**Time-Cap Labs Inc**

7 Michael Avenue Farmingdale NY 11735

**BULK SHIPMENT INTENDED FOR MANUFACTURING,  
PROCESSING OR REPACKAGING**

TCL Control #

THEORETICAL QUANTITY:

CTN#      OF      CTNS.

NDC 49483-011-00

Product **ASPIRIN TABLETS USP, 325 MG (MICRO  
COATED CLEAR)**

DEBOSSSED: TCL 011

Each Tablet Contains: ASPIRIN 325 MG

**STORE AT 25°C (77°F) - Excursions permitted between  
15°-30°C (59°-86°F) IN ORIGINAL BULK CONTAINERS**

**REPACKAGE IMMEDIATELY UPON RECEIPT**

**IMPORTANT**

This is a bulk shipment intended to be repackaged and labeled immediately upon receipt in strict conformance with the applicable requirements of the Food, Drug and Cosmetic Act, and regulations thereunder or the laws and regulations of the country of destination.

Upon request Time-Cap Labs will supply stability supported packaging specifications. Our responsibility ceases upon removal of the product from the bulk containers or failure to request or follow Time-Cap Labs packaging and/or labeling specifications.

**Ship To:**

TRSYSDYTEDYDUDUYFIFUUGOGOGIIOGOIGOIGIOIO



NDC 49483-011-10

ime-Cap Labs, Inc.

Micro-Coated

Aspirin (NSAID) 325 mg (5 gr)

\*\*Compare to the active ingredient in Genuine Bayer\*

Analgesic/Pain Reliever

easy to swallow

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

1000 Tablets



Drug Facts

Active ingredient (in each tablet) Purpose Aspirin 325 mg (NSAID)\* ..... Pain reliever \*nonsteroidal anti-inflammatory drug

Uses

- for the temporary relief of minor aches and pains due to headache, colds, menstrual pain, muscle pain, toothache, minor pain of arthritis or as directed by your doctor

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)

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- have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, have 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed

Drug Facts (continued)

Do not use if you are 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 asthma, you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, you are taking a diuretic, 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: have bloody or black stools, vomit blood, 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

Drug Facts (continued)

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

\*\*This product is not manufactured or distributed by The Bayer Corp., owner of the registered trademark Genuine Bayer®

Manufactured by: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735



TAMPER EVIDENT. DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL IS CUT, TORN, BROKEN OR MISSING

LOT #: EXP. DATE:

ime-Cap Labs, Inc.

See New Warnings Information

Micro-Coated Aspirin (NSAID) 325 mg (5 gr)

\*\*Compare to the active ingredient in Genuine Bayer\*

Analgesic/Pain Reliever

easy to swallow

100 Tablets



This product is not manufactured or distributed by The Bayer Corp., owner of the registered trademark Genuine Bayer®. Manufactured by Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735



Drug Facts Active ingredient (in each tablet) Purpose Aspirin 325 mg (NSAID)\* ..... Pain reliever \*nonsteroidal anti-inflammatory drug

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PEEL HERE FOR MORE DRUG FACTS

LOT #: EXP. DATE:

Drug Facts (continued)

Do not use if you are 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: feel faint, have bloody or black stools, vomit blood, 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

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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

STOP PEELING

ASPIRIN

aspirin tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-011
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL011
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49483-011-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2014	
2	NDC:49483-011-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2014	
3	NDC:49483-011-00	100000 in 1 CARTON; Type 0: Not a Combination Product	04/02/2014	
4	NDC:49483-011-31	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2023	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M013	04/02/2014	

**Labeler** - TIME CAP LABS INC (037052099)

**Registrant** - TIME CAP LABS INC (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-011)

Revised: 11/2023

TIME CAP LABS INC