

ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, delayed release

Time-Cap Labs, Inc

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.

331R Timely 49483-331 Aspirin 325mg Delayed Release Tablets

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID*) *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporarily relieves minor aches and pains due to:

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

or as recommended by a 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
- 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

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 diabetes, gout, or 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

have bloody or black stools

vomit blood

have stomach pain that does not get better

- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

These could be signs of a serious condition.

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- **each tablet contains:** sodium 1 mg (VERY LOW SODIUM)
- 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, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium

hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments? call 1-877-290-4008

timely™


NDC 49483-331-10
*Compare to the active ingredient in Ecotrin®

Regular Strength
Aspirin
325 mg Delayed-Release Tablets
Pain Reliever (NSAID)


THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Safety Coated Aspirin Regimen

1000 ENTERIC COATED TABLETS



Actual Size

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Aspirin 325 mg (NSAID)* Pain Reliever Nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache muscle pain toothache menstrual pain colds minor arthritis pain <p>or as recommended by a doctor</p> <p>Warnings</p> <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction, which may include: <ul style="list-style-type: none"> hives facial swelling shock asthma (wheezing) </p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: <ul style="list-style-type: none"> 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 </p>	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> if you are allergic to aspirin or any other pain reliever/fever reducer <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking a prescription drug for diabetes, gout, or arthritis <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> an allergic reaction occurs. Seek medical help right away. you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> 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 redness or swelling is present new symptoms occur ringing in the ears or a loss of hearing occurs <p>These could be signs of a serious condition.</p> <p>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.</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>
<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> 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 <p>Other information</p> <ul style="list-style-type: none"> each tablet contains: sodium 1 mg (VERY LOW SODIUM) store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) use by expiration date on package <p>Inactive ingredients corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, mineral oil, poly sorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate</p> <p>Questions or comments? call 1-877-290-4008</p> <p style="border: 1px solid red; padding: 2px; display: inline-block;">TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING</p> <div style="text-align: center;">  <p>3 49483 33110 3</p> </div>	

This product is not manufactured or distributed by Prestige Brands, Inc., owner of the registered trademark Ecotrin®, 331R 0821
Manufactured by: Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735

LOT #: _____
EXP. DATE: _____

Varnish Omit Area

ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-331
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg in 325

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-331-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2011	
2	NDC:49483-331-00	100000 in 1 CARTON; Type 0: Not a Combination Product	04/10/2011	
3	NDC:49483-331-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	01/04/2011	

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(49483-331)

Revised: 1/2022

Time-Cap Labs, Inc