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.

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

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
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  - 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

corn starch, croscarmellose sodium,D-C yellow #10 aluminum lake, FD-C yellow#6 aluminum lake,

hypromellose, methacrylic acid copolymer, microcrystalline cellulose,mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Use for the temporary relief of minor aches and pains due to:

headache, colds, muscle pain, menstrual pain, toothache, minor pain of arthritis or as directed by your doctor

Pain Reliever

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, asthmaaa9wheezing)

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.

In each Tablet Asprin 325 mg (NSAID*) *non-steroidal anti-inflammatory drug

ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, delayed release

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (ASPIRIN)	ASPIRIN	325 mg in 325

Inactive Ingredients

Ingredient Name	Strength
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE)	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
CELLULOSE, MICROCRYSTALLINE	
MINERAL OIL	
POLYSORBATE 80	
DIMETHICONE	
SILICON DIOXIDE	
SODIUM HYDROXIDE	
SODIUM LAURYL SULFATE	
TALC	
TITANIUM DIOXIDE	
TRIETHYL CITRATE	
HYPROMELLOSES	

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		
2	NDC:49483-331-00	100000 in 1 CARTON		
3	NDC:49483-331-10	1000 in 1 BOTTLE, PLASTIC		

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)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-331)