

**ASPIRIN EXTRA STRENGTH- aspirin tablet, coated**  
**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.*

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**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 lost a lot of fluid due to vomiting or diarrhea
- 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
  - 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, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

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/fever reducer

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.

In each Tablet Aspirin 500 mg (NSAID\*) \*non-steroidal anti-inflammatory drug

**Adhesive Area**

**Drug Facts (continued)**

(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 are taking a diuretic ■ you have asthma ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease  
 ■ you have lost a lot of fluid due to vomiting or diarrhea  
 ■ 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  
 ■ 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 ■ vomit blood  
 ■ have bloody or black stools  
 ■ have stomach pain that does not get better  
 ■ pain gets worse or lasts more than 10 days  
 ■ redness or swelling is present in the painful area  
 ■ fever gets worse or lasts more than 3 days  
 ■ 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 explicitly 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 to 6 hours, while symptoms last. Do not exceed 8 tablets in 24 hours  
 ■ 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, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

**STOP PEELING**

Time-Cap Labs, Inc. NDC 49483-382-01  
 'Compare to the active ingredient in Bayer® Extra Strength

**Extra Strength ASPIRIN** ASPIRIN REGIMEN  
 Safety Coated

**500mg**  
 Pain Reliever (NSAID)  
 Fever Reducer

**100 COATED TABLETS** New Improved Formula

This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Bayer, Extra Strength, 382R, 1112. Manufactured by Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735

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**Drug Facts**  
**Active ingredient (in each tablet)**  
 Aspirin 500 mg (NSAID)\* ..... Pain reliever/fever reducer  
 \*nonsteroidal anti-inflammatory drug

**Uses** temporarily relieves ■ headache ■ muscle pain  
 ■ pain and fever of colds ■ menstrual pain  
 ■ minor pain of arthritis ■ toothache

**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 ■ shock ■ facial swelling ■ 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

**LOT #:** \_\_\_\_\_  
**EXP. DATE:** \_\_\_\_\_

**FOR MORE DRUG FACTS, PLEASE PEEL HERE**

# ASPIRIN EXTRA STRENGTH

aspirin tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-382
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg in 500

## Inactive Ingredients

Ingredient Name	Strength
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<b>MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE)</b> (UNII: 461P5CJN6T)	
<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)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL382
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-382-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:49483-382-00	100000 in 1 CARTON		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/11/2013	

**Labeler** - Time-Cap Labs, Inc (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-382)