

## **REGULAR STRENGTH ASPIRIN EC- aspirin tablet, delayed release**

### **A-S Medication Solutions**

*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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### **Drug Facts**

#### **Active ingredient**

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

#### **Purpose**

Purpose  
Pain reliever

#### **Uses**

- Uses
  - 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

#### **Warnings**

- 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 or 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**

- Do not use
  - if you are allergic to aspirin or any other pain reliever/fever reducer

### **Ask Doctor**

- 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 Doctor/Pharmacist**

- Ask a doctor or pharmacist before use if you are
  - taking a prescription drug for diabetes, gout, or arthritis
  - taking any other drugs
  - under a doctor's care for any serious condition

### **Stop Use**

- 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

### **Pregnancy or Breast Feeding**

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.

### **Directions**

- 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

### **Keep Out of Reach of Children**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **Storage and Handling**

- 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**

Inactive ingredients 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

### **Questions**

Questions? To Report Adverse Drug Event Call: (800) 616-2471

### **HOW SUPPLIED**

Product: 50090-3450

NDC: 50090-3450-1 30 TABLET, DELAYED RELEASE in a BOTTLE

## Aspirin



### REGULAR STRENGTH ASPIRIN EC

aspirin tablet, delayed release

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-3450(NDC:0904-2013)
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

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

#### Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPAS) (UNII: 36SFW2JZ0W)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

<b>Product Characteristics</b>			
<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	T
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3450-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/09/2011	

**Labeler** - A-S Medication Solutions (830016429)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3450) , REPACK(50090-3450)