# **ENTERIC COATED ASPIRIN - regular strength tablet 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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### **Enteric Coated Aspirin Regular Strength**

# **ACTIVE INGREDIENTS (IN EACH TABLET)**

Aspirin 325mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

#### **PURPOSE**

Pain reliever

#### **USES**

for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its** delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

#### **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
- asthma (wheezing)
- shock

**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 other pain relievers/fever reducers

#### 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 have asthma
- you are taking a diuretic

# Ask a doctor or pharmacist before use if you are

taking a prescription drug for:

- anticoagulation (thinning the blood)
- diabetes
- gout
- 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, vomit blood, have bloody or black stools, have stomach pain that does not get better
- new symptoms occur
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days

# 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 specifically 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 or 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

#### OTHER INFORMATION

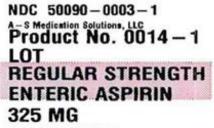
- store at room temperature
- do not use if imprinted safety seal under cap is broken or missing

You may report serious side effects to: 1-888-952-0050

#### **INACTIVE INGREDIENTS**

corrn starch, croscarmellose sodium, Dimethicone, D&C Yellow # 10 aluminum lake, FD&C Yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

# **Regular Strength**



EACH TABLET CONTAINS
ASPIRIN 325 MG (NSAID\*)
STORE AT ROOM TEMPERATURE
30 ENTERIC COATED
TABLETS



## **ENTERIC COATED ASPIRIN**

regular strength tablet

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-0003(NDC:0603-0169)		
Route of Administration	ORAL				

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TALC (UNII: 7SEV7J4R1U)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MINERAL OIL (UNII: T5L8T28FGP)	

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

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:50090-0003-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014		
2	NDC:50090-0003-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014		
3	NDC:50090-0003-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	02/04/2011	

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

Establishment			
Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0003), REPACK(50090-0003)

Revised: 8/2017 A-S Medication Solutions