

## **ASPIRIN ENTERIC COATED- aspirin 325 mg tablet**

### **Allegiant Health**

*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**

Aspirin 325 mg (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 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 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 pain gets worse or lasts more than 10 days redness or swelling is present new symptoms occur ringing in the ears or loss of hearing occurs  
You may report side effects to 1-888-952-0050

**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 accidental overdose, get medical help or contact a PoisonControlCenter right away.

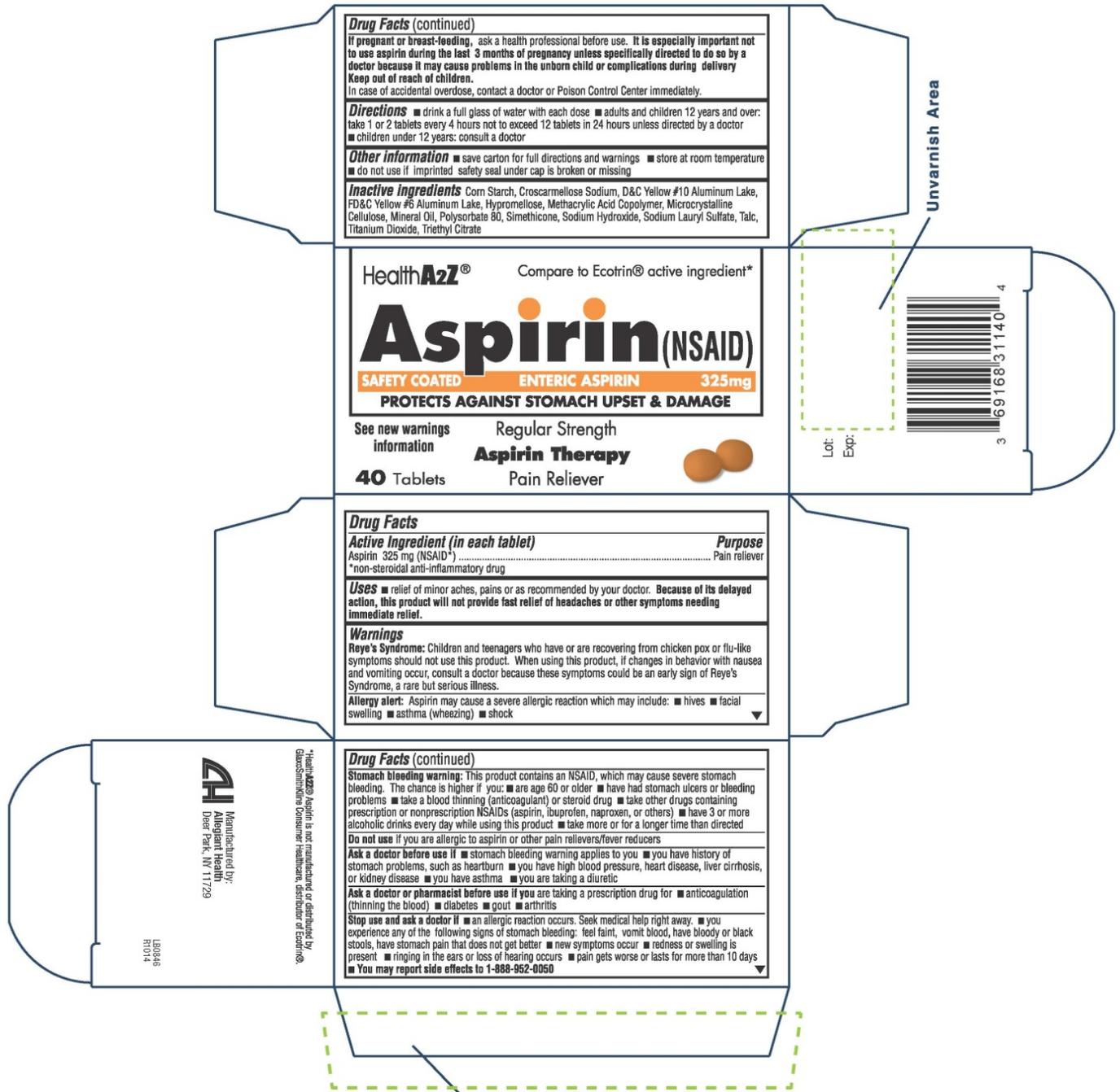
**Directions**

- drink a full glass of water with each dose
- **adults and children 12 years and over:** take 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- **children under 12 years:** consult a doctor

**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

**Package/Label Principal Display Panel**



## ASPIRIN ENTERIC COATED

aspirin 325 mg tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-331
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	

## Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	A
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-331-40	40 in 1 CARTON; Type 0: Not a Combination Product	12/18/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	12/18/2014	

**Labeler** - Allegiant Health (079501930)

**Registrant** - Allegiant Health (079501930)

## Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	LABEL(69168-331) , PACK(69168-331) , RELABEL(69168-331) , REPACK(69168-331) , MANUFACTURE(69168-331)

