ASPIRIN- aspirin tablet
CARDINAL 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.

Drug Facts

Active ingredient (in each tablet)

Aspirin 325mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

- Temporarily relieves minor aches and pains due to • colds • headache • muscle pain • menstrual pain • minor pains of arthritis • toothache
- or as receommended by your doctor

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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

Do not use

if you have ever had an allergic reaction 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

Ask a doctor or pharmacist before use if you are

taking a prescription drug for
- gout
- diabetes
- 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
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious illness.

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 accidental 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 persist. Do not exceed 12 tablets in 24 hours unless diretced by a physician.
children under 12 years	consult a physician

Other information
- avoid excess heat and moisture
- store below 25^0 C (77^0 F)

Inactive ingredients

croscarmellose sodium, D&C yellow #10 Lake, FD&C red #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, propylene glycol, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin.

Questions or comments?

Adverse drug event call: 1-866-562-2756

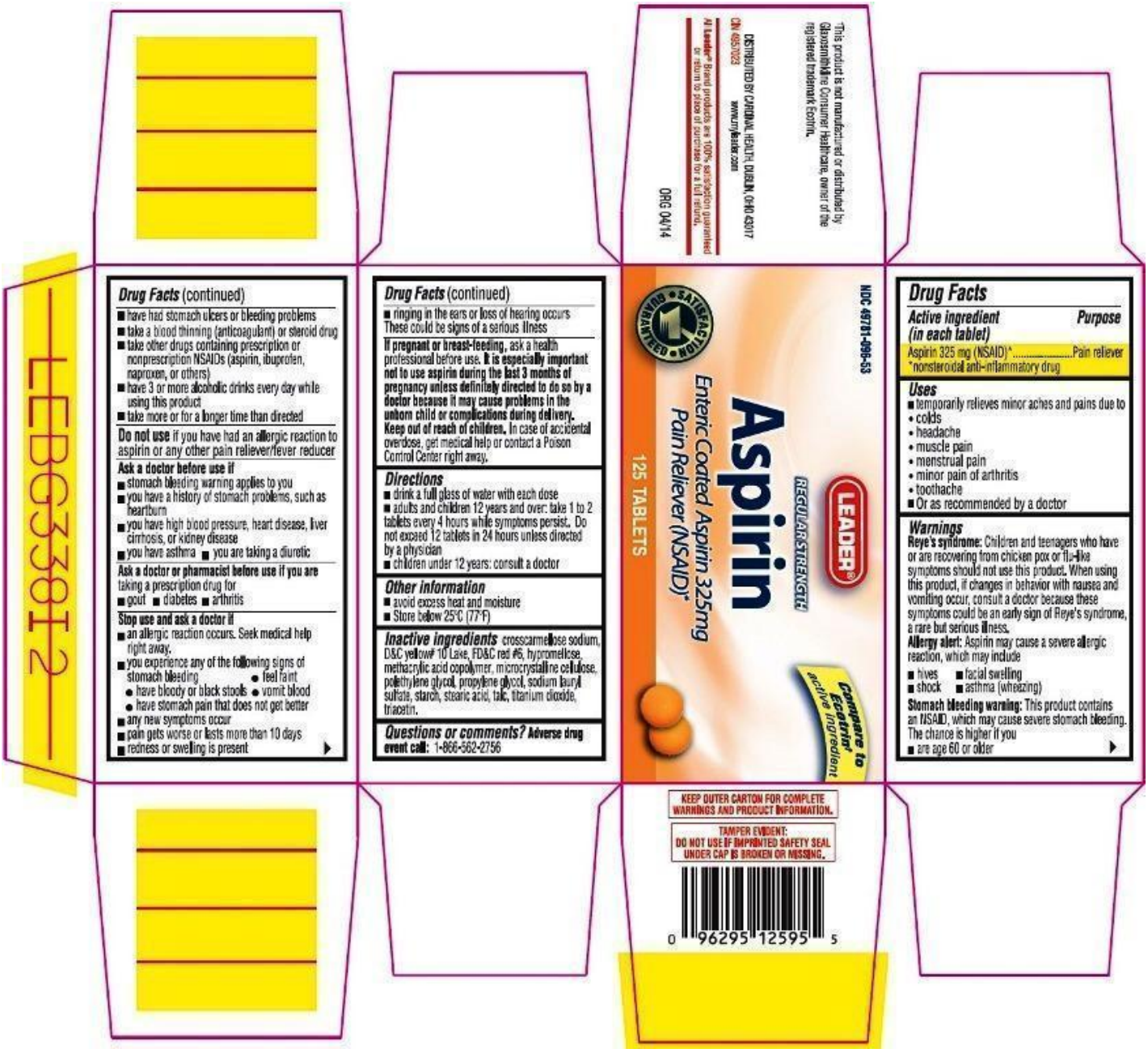
†Compare to Ecotrin® active ingredient

Leader

Regular Strength Aspirin

Enteric Coated Aspirin 325 mg

Pain Reliever (NSAID)



ASPIRIN

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-096
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 6 (UNII: 481744AI4O)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	PH024
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49781-096-53	1 in 1 CARTON		
1		125 in 1 BOTTLE		
2	NDC:49781-096-58	300 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/20/2014	

Labeler - CARDINAL HEALTH (097537435)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)