ASPIRIN - aspirin tablet, delayed release
Sunrise Pharmaceutical 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.

Aspirin 81 mg Pain reliever

OTC - ACTIVE INGREDIENT

Aspirin 81 mg (NSAID) nonsteroidal anti-inflammatory drug

OTC - PURPOSE

Pain reliever.

INDICATIONS AND USAGE

For temporary relief of minor aches and pains or as recommended by your doctor.

Because of its delayed release 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.

OTC - ASK 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.

OTC - ASK DOCTOR/PHARMACIST

Before use if you are taking a prescription drug for**:**

gout

diabetes

arthritis

OTC - 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,

allergic reaction occurs seek medical help right away,

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.

OTC - PREGNANCY 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.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DOSAGE AND ADMINISTRATION

Drink with a full glass of water with each dose

Adults and children 12 years and over	Take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
Children under 12 years	Consult a doctor

OTHER INFORMATION

Store at 15°-30°C (59°-86°F). Do not use if imprinted seal under cap is missing or damaged.

INACTIVE INGREDIENT

Anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulphate, talc, titanium dioxide, triethyl citrate.

.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

5.125" WIDTH

ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11534-155
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE (UNII: J2B2A4N98G)	

CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	heart
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11534-155-11	120 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	01/03/2010	

Labeler - Sunrise Pharmaceutical Inc (168522378)

Revised: 1/2011 Sunrise Pharmaceutical Inc