

**VALUE PHARMA ASPIRIN PAIN RELIEVER- aspirin tablet**  
**Ajes Pharmaceuticals,LLC**

*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**

**ASPIRIN**

**Inactive Ingredients**

In case of over dose get medical help and contact a Poison Control Center immediately.

For temporary relief of minor aches and pains or as recommended by your Doctor. Because of this products delayed release action, this product will not provide fast relief of headaches or symptoms needing immediate relief.

Do not use if you have ever had an allergic reaction to any other pain relievers/fever reducers. Children or teenagers who are recovering from the Chicken Pox or flu like symptoms should not use this product. When using this product if changes in behavior occur with nausea and vomiting occur,consult a Doctor because this could be a sign of Reye's Syndrome, a rare but serious illness.

**Directions** - drink a full glass of water with each dose. Adults and children 12 years of age and over: take 4 to 8 tablets every 4 hours not to exceed48 tablets in 24 hours unless directed by a doctor. Children under 12 years: consult a doctor

<b>Drug Facts</b>	<b>Purpose</b> Aspirin 81 mg.....Pain reliever
<b>Active Ingredient (in each tablet)</b> Aspirin 81 mg.....Pain reliever	<b>Uses</b> for the 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.
<b>Do not use if you have ever had an allergic reaction to any other pain relievers/ fever reducers.</b>	<b>Warnings</b> <b>Reyes syndrome:</b> 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.
<b>Ask a doctor before use if you have -stomach problems (such as heartburn, upset stomach, or stomach pain) that last or come back -bleeding problems- ulcers -asthma</b>	<b>Ask a doctor or pharmacist before use if -you are taking a prescription drug for -diabetes- gout- arthritis</b>
<b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include- facial swelling, asthma (wheezing), -shock -hives	<b>Alcohol warning</b> if you consume 3 or more alcoholic drinks every day. Ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.
<b>Stop use and ask doctor if an 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</b>	<b>If pregnant or breast-feeding</b> 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.
<b>Keep out of the reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center immediately.	<b>Directions</b> -drink a full glass of water with each dose. -Adults and children 12 years of age 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
<b>Other information</b> store at room temperature	<b>Inactive Ingredients</b> colloidal silicon dioxide, croscarmellose sodium, FD&C Yellow #10 al lake, FD&C Yellow #6 al lake, methacrylic acid copolymer, microcrystalline cellulose, stearic acid, talc, titanium dioxide, triethyl citrate

**Purpose**

Pain Reliever

<b>VALUE PHARMA ASPIRIN PAIN RELIEVER</b>			
aspirin tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42787-101
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	81 mg in 81 mg

**Inactive Ingredients**

Ingredient Name	Strength
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Triethyl Citrate (UNII: 8Z96QXD6UM)	

**Product Characteristics**

Color	yellow (Yellow color)	Score	no score
Shape	ROUND (Round Pill)	Size	6mm
Flavor		Imprint Code	C3
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42787-101-50	1 in 1 CARTON		
1		4050 mg in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/01/2012	

**Labeler** - Ajes Pharmaceuticals,LLC (159945393)**Establishment**

Name	Address	ID/FEI	Business Operations
Ajes Pharmaceuticals,LLC		159945393	manufacture(42787-101)