

VALUE PHARMAPAIN RELIEVER EXTRA STRENGTH- 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

Active Ingredient (in each tablet)

Aspirin 325 mg (NSAID)*

nonsteroidal antiinflammatory drug

Inactive Ingredients Hydroxypropylmethyl cellulose, polyethylene glycol, starch, talc, titanium dioxide

Purpose

Pain reliever / Fever reducer

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately

Uses provides temporary relief of: headache pain and fever of colds - muscle pain - toothache - minor pain of arthritis

Warnings

Do not use - if you have ever had an allergic reaction to any other pain relievers/fever reducers.

Reyes 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 or 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 : facial swelling - asthma (wheezing) - shock - hives

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chances are higher if you are- 60 years of age or older - have had stomach ulcer bleeding problems - take a blood thinner (anticoagulant) or steroid drug - take other drugs containing prescription or non prescription NSAIDs (aspirin, ibuprofen, naproxen, others) - have 3 or more alcoholic drinks everyday while using this product - take more or for a longer time than directed

Directions - drink a full glass of water with each dose - Adults and children 12 years of age and over: take 1 to 2 tablets with water. Dosage may be repeated every 4 hours, not to exceed 12 tablets in 24 hours. Children under 12: consult a doctor

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 or complications during delivery

Drug Facts

Active Ingredient (in each tablet) **Purpose**
 Aspirin 325 mg(NSAID)*Pain reliever/
 * nonsteroidal anti-inflammatory drug Fever reducer

Uses provides temporary relief of: -headache pain and fever of colds -muscle pain -menstrual pain -toothache -minor pain of arthritis

Warnings
Do not use -if you have ever had an allergic reaction to any other pain relievers/ fever reducers.

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Ask a doctor before use if the stomach bleeding warning applies to you ▶

NDC 42787-102-12

Value/Pharma +

EASY to swallow

Pain Reliever Regular Strength

Fever Reducer

325 mg (NSAID)* **ASPIRIN**

* non steroidal anti-inflammatory drug

FILM COATED WHITE TABLETS

1000 TABLETS

Drug Facts Continued

If you have a history of stomach problems, such as heartburn -liver cirrhosis -asthma -high blood pressure -heart or kidney disease -taken a diuretic

Ask a doctor or pharmacist before use if you are -taking any other drug containing an NSAID (prescription or nonprescription) -taking a blood thinning (anticoagulant) or steroid drug -taking a prescription drug for diabetes, gout or arthritis

Stop use and ask 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 -an allergic reaction occurs. Seek help right away -pain gets worse or lasts more than 10 days -redness or swelling is present -fever gets worse or lasts more than 3 days -any new symptoms occur -ringing in the ears or loss of hearing occurs

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 the reach of children. In case of overdose overdose, get medical help or contact a Poison Control Center immediately.

Directions -drink a full glass of water with each dose. -Adults and children 12 years of age and over: take 1 to 2 tablets with water. Dosage may be repeated every 4 hours, not to exceed 12 tablets in 24 hours. Children under 12: consult a doctor

Other Information -store at room temperature

Inactive Ingredients Hydroxypropylmethyl cellulose, polyethylene glycol, starch, talc, titanium dioxide

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 aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42787-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	325 mg in 325 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
talc (UNII: 7SEV7J4RIU)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white color)	Score	no score
Shape	ROUND (Round Tablet)	Size	11mm
Flavor		Imprint Code	C10

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42787-102-12	1 in 1 CARTON		
1		325000 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(42787-102) , relabel(42787-102) , repack(42787-102)

Revised: 5/2014

Ajes Pharmaceuticals,LLC