

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

Value/Pharma  NDC 42787-102-50

EASY to swallow **Pain Reliever Regular Strength**

Fever Reducer

325 mg (NSAID)* **ASPIRIN** **FILM COATED WHITE TABLETS** **50 TABLETS**

* non-steroidal anti-inflammatory drug

Drug Facts

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

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 reliever/ 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 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: 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 or bleeding problems, take blood thinners (anticoagulants) or salicylates, use other drugs (prescription or over-the-counter NSAIDs, aspirin, ibuprofen, naproxen or others) have 3 or more alcoholic drinks a day, while using this product, take more or for a longer time than directed.

Ask a doctor before use if the stomach bleeding warning applies to you
If you have a history of stomach problems, such as heartburn, liver cirrhosis, asthma, high blood pressure, heart or kidney disease
Do not take if you are taking any other drug containing an NSAID (prescription or nonprescription)
Do not take if you are 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: black, tarry stools; blood in body fluids; 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, 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 4 times a day. Do not 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

VALUE PHARMAPAIN RELIEVER EXTRA STRENGTH

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:42787-102-50	1 in 1 CARTON		
1		16250 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: 11/2012

Ajes Pharmaceuticals,LLC