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.

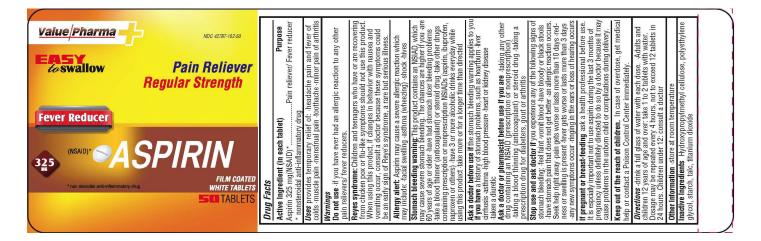
Reyes Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea or vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's Syndrome, a rare but serious illness.

Allergy Alert: Aspirin may cause a sever 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



VAL aspirin		MAPAIN	RELIEVER EX	TRA ST	RENGTH		
Prod	uct Informati	ion					
Produ	ıct T yp e		HUMAN OTC DRUG	Iten	Item Code (Source)		NDC:42787-102
Route	of Administrat	ion	ORAL				
Activ	e Ingredient/	Active Moi	ety				
	-	Ingredie	Basis of Strength		Strength		
Aspiri	n (UNII: R16CO5Y	76E) (Aspirin -	UNII:R16CO5Y76E)		Aspirin		325 mg in 325 mg
Inact	ive Ingredier	nts					
muet		Strength					
HYPRO							
	ETHYLENE GLY						
STAR	C H, CORN (UNII:	O8232NY3SJ)					
talc (U	NII: 7SEV7J4R1U)					
Titani	Titanium Dioxide (UNII: 15FIX9V2JP)						
Prod	uct Characte	ristics					
Color		white (white color)			Score		no score
Shape	2	ROUND (Round Tablet)			Size		11mm
Flavor	1				Imprint Code		C10
Conta	ins						
Pack	aging						
#	Item Code	Pac	kage Description	Marke	ting Start Date	Mai	rketing End Date
1 NDC	2:42787-102-50	1 in 1 CAI			2		
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