ASPIRIN- aspirin tablet
Rebel Distributors Corp

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 Drug Facts

Active ingredient

Aspirin 325mg

Purpose

Pain Reliever

Keep Out of Reach of Children

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

Uses

For the temporary relief of minor aches and pains. Ask your doctor about other uses for aspirin.

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 or 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) or 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.

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if ° the stomach bleeding warning applies to you ° you are taking a diuretic ° you have a history of stomach problems such as heartburn ° you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma.

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 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, an allergic reaction occurs. Seek medical help right away if 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, or 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.

Directions

Drink a full glass of water with each dose. Swallow whole; do not chew or crush. Do not exceed recommend dose.

Adults and children 12 years and older: take 1-2 tablets every 4 hours, as needed, not more than 12 tablets in 24 hours, or as directed by a doctor.

Children under 12: ask a doctor.

Other Information

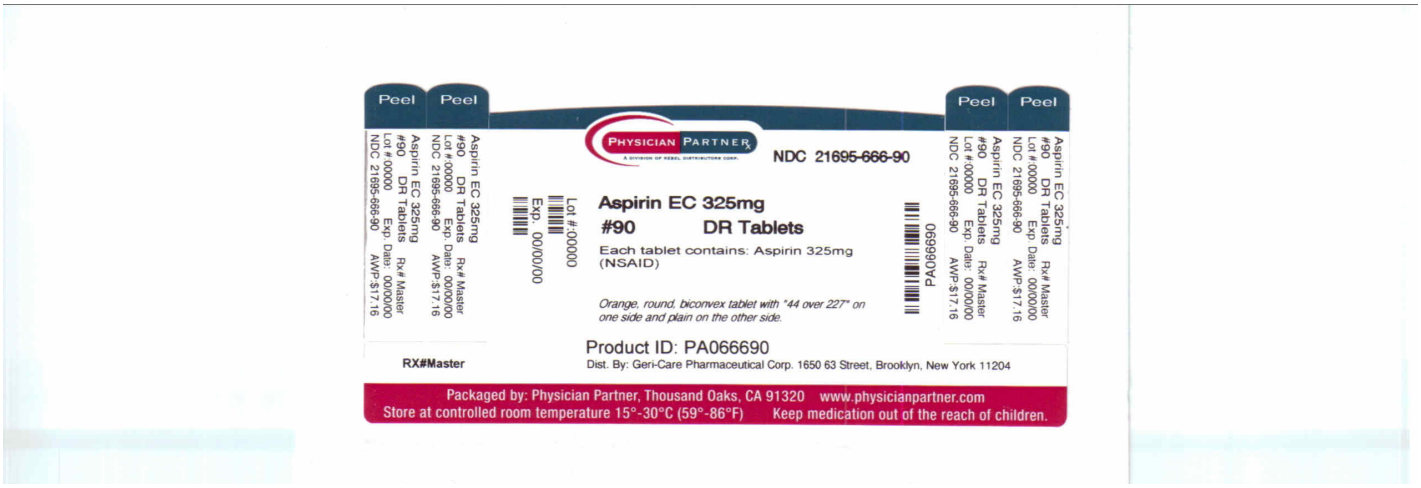
Store at room temperature, 15°C - 30°C (59°F - 86°F).

For institutional use only.

Inactive ingredients

May contain acetylated monoglycerides, cellulose, croscarmellose sodium, D&C yellow no. 10, FD&C yellow no. 6, hypromellose, hypromellose phthalate, iron oxide, methacrylic acid, mineral oil, PEG, polydextrose, polysorbate 80, polyvinyl acetate phthalate, propylene glycol, silica sodium alginate, sodium bicarbonate, sodium lauryl sulfate, starch stearic acid, talc, titanium dioxide, triacetin, triethyl citrate, wax.

Package/Label Principal Display Panel



ASPIRIN

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-666(NDC:57896-401)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-666-30	30 in 1 BOTTLE		
2	NDC:21695-666-90	90 in 1 BOTTLE		
3	NDC:21695-666-00	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/07/2008	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011 Rebel Distributors Corp