

ASPIRIN- aspirin tablet, film coated
Contract Pharmacy Services-PA

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 Tablets

DRUG FACTS

ACTIVE INGREDIENT (IN EACH TABLET)

Aspirin 325 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USES

Temporarily relieves minor aches and pains associated with

- headache
- minor arthritis
- common cold
- menstrual cramps
- muscular aches
- backache
- toothache

Temporarily reduces fever.

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 of 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)
- shock

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if

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
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- any new symptoms appear
- 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 reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DIRECTIONS

- do not take more than directed
- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

Adults and childre: (12 years and older)

Take 1 or 2 tablets with water every 4 hours as needed. Do not take more than 12 tablets in 24 hours, or as directed by a doctor.

Children under 12 years:

Do not give to children under 12 years of age.

OTHER INFORMATION

store at 15° to 30°C (59° to 86°F)

Inactive Ingredients

ma contain acetylated monoglycerides, cellulose, croscarmellose sodium, D&C yellow #10 lake, FD&C yellow lake #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.

QUESTIONS OR COMMENTS?

Distributed by:

GERI-CARE PHARMACEUTICALS CORP.

1650 63 Street, Brooklyn, New York 11204

Repackaged by:

Contract Pharmacy Services-PA

125 Titus Ave Suite 200

Warrington, PA 18976 USA

Original--08/2010--NJW

Package Label

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;227
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-164-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/01/2010	

Labeler - Contract Pharmacy Services-PA (945429777)