

ASPIRIN LOW DOSE- 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 Low Tablets

DRUG FACTS

ACTIVE INGREDIENT (IN EACH TABLET)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever

USES

- for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product may not provide fast relief of headache or other symptoms needing immediate relief.
- ask your doctor about other uses for this product

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

- drink a full glass of water with each dose
- do not exceed recommended dosage
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

OTHER INFORMATION

store at 20° to 25°C (68° to 77°F)

Inactive Ingredients

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D-C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide

QUESTIONS OR COMMENTS?

Distributed by:

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150

Repackaged by:

Contract Pharmacy Services-PA

125 Titus Ave Suite 200

Warrington, PA 18976 USA

Original--08/2010--NJW

Package Label

E.C. ASA LOW DOSE
81MG TAB #30

LOT# SAMPLE
ID: (HEART)
EXP: 11/11
MAJOR

USUAL DOSAGE:
SEE INSERT

STORAGE
CONDITIONS:
SEE INSERT
(STORE AT
CONTROLLED
ROOM
TEMPERATURE)

FILLED BY _____
CHECKED BY _____
Packaged By: Contract Pharmacy Services-PA
125 Titus Avenue, Suite #200, Warrington, PA 18976

MED. _____
STRENGTH _____
EXP. DATE _____
MFG. _____
LOT NO. _____

Contract Pharmacy Services

CAUTION: This package NOT CHILD RESISTANT. Store this and all medications out of reach of children.

0510MS 1300PS

Blister of 30 Tablets

ASPIRIN LOW DOSE

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-168(NDC:0904-7704)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
IRON (UNII: E1UOL152H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-168-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/03/2010	

Labeler - Contract Pharmacy Services-PA (945429777)