

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 20° to 25°C (68° to 77°F)

QUESTIONS OR COMMENTS?

Distributed by: Marlex Pharmaceuticals, 50 McCullough Drive, New Castle, DE 19720, U.S.A.

call toll free **1-866-820-7381**

Repackaged by:

Contract Pharmacy Services-PA

125 Titus Ave Suite 200

Warrington, PA 18976 USA

Original--08/2010--NJW

Package Label

E.C.ASPIRIN
325 MG TAB #30

USUAL DOSAGE:
SEE INSERT

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

LOT# SAMPLE
ID: T
EXP: 04/11

MARLEX

FILLED BY _____

CHECKED BY _____

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.

Blister of 30 Tablets

ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-162(NDC:10135-126)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67046-162-30	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	08/10/2010	

Labeler - Contract Pharmacy Services-PA (945429777)

Revised: 7/2010

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