# ASPIRIN LOW DOSE- as pirin 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.

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#### **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

Acetylated monoglycerides, anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, D&C Yellow 10, hypromellose, hypromellose phthalate, iron oxide ochre, microcrystalline cellulose, mineral oil, polyethylene glycol 400, polysorbate 80, titanium dioxide.

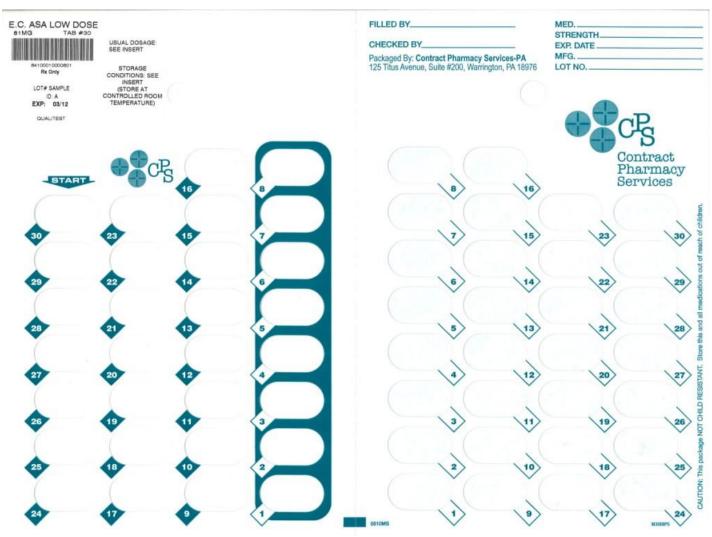
#### **QUESTIONS OR COMMENTS?**

Distributed by: Qualitest Pharmaceuticals, 130 Vintage Drive, Huntsville, AL 35811, U.S.A.

Repackaged by:

Contract Pharmacy Services-PA 125 Titus Ave Suite 200 Warrington, PA 18976 USA Original--08/2010--NJW

## Package Label



Bliste of 30 Tablets

ASPIRIN LOW DOSE			
aspirin tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-163(NDC:0603-0026)
Route of Administration	ORAL		

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

<b>Product Characteristics</b>	t Characteristics			
Color	YELLOW	Score	no score	
Shape	ROUND	Size	8 mm	
Flavor		Imprint Code		
Contains				

ı	Packaging	kaging		
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
١	1 NDC:67046-163-30	30 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/17/2010	

# Labeler - Contract Pharmacy Services-PA (945429777)

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