ASPIRIN- as pirin tablet Qualitest Pharmaceutical, Inc.

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.

Low Dose Aspirin 81 mg (Delayed-Release Enteric Coated)

ACTIVE INGREDIENTS (IN EACH TABLET)

Aspirin 81mg (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 will not provide fast relief of headaches or other symptoms needing immediate relief.

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 very serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

if an allergic reaction occurs, stop use and seek medical help right away.

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 other pain relievers/fever reducers

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 have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

Taking a prescription drug for:

- anticoagulation (thinning of the blood)
- diabetes
- gout
- 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
- new symptoms occur
- redness or swelling is present
- Ringing in the ears or loss of hearing occurs
- Pain gets worse or lasts for more than 10 days

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 specifically 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

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

DIRECTIONS

- drink a full glass of water with each dose
- 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: consult a doctor

OTHER INFORMATION

- store at room temperature
- do not use if imprinted safety seal under cap is broken or missing

You may report side effects to: 1-888-952-0050.

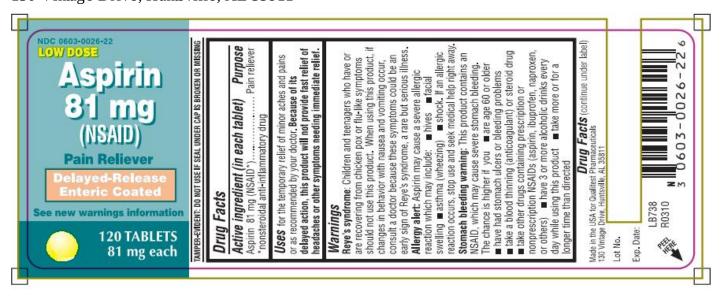
INACTIVE INGREDIENTS

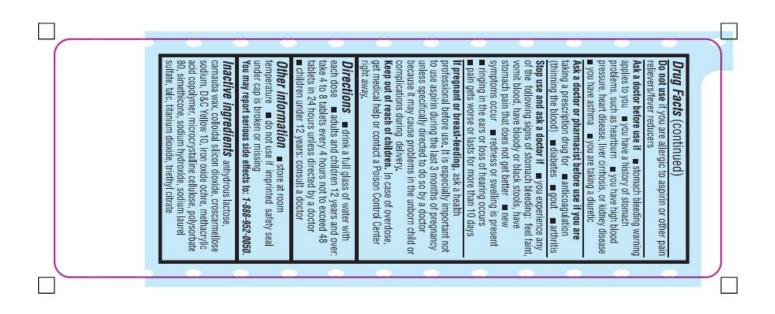
Anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Yellow 10, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium laurel sulfate, talc, titanium dioxide, triethyl citrate

PRINCIPAL DISPLAY PANEL

Pain Reliever

Delayed-Release Enteric Coated Made in USA for Qualitest Pharmaceuticals 130 Vintage Drive, Huntsville, AL 35811







Directions ■ drink a full glass of water with each dose
■ 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: consult a Keep out of reach of children. In case of overdose, get directed to do so by a doctor because it may cause problems in the unborn child or complications during is present ringing in the ears or loss of hearing occurs pain gets worse or lasts for more than 10 days Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ anticoagulation (thinning the blood) Yellow 10, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium laurel sulfate, talc, titanium Other information ■ store at room temperature ■ do not use if imprinted safety seal under cap is broken or during the last 3 months of pregnancy unless specifically If pregnant or breast-feeding, ask a health professiona have bloody or black stools, have stomach pain that does not get better a new symptoms occur redness or swelling following signs of stomach bleeding: feel faint, vomit blood, have bloody and prescription drug for anticoagulation diabetes gout arthritis You may report serious side effects to 1-888-952-0050 Drug Facts (continued Inactive ingredients anhydrous lactose, carnauba before use. It is especially silicon dioxide, croscarmellose sodium, D&C important not to use aspirin

ASPIRIN

aspirin tablet

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0603-0026	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (ASPIRIN)	ASPIRIN	81 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX	
ANHYDRO US LACTO SE	

COLLOIDAL SILICON DIO XIDE	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
POLYSORBATE 80	
SO DIUM HYDRO XIDE	
TALC	
TITANIUM DIO XIDE	
TRIETHYL CITRATE	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
DIMETHICONE	
FERRIC O XIDE RED	

Product Characteristics				
Color	yello w	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	A	
Contains				

1	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0603-0026-22	120 in 1 BOTTLE			
2	NDC:0603-0026-32	1000 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	11/03/2009		

Labeler - Qualitest Pharmaceutical, Inc. (011103059)

Registrant - A&Z Pharmaceutical, Inc. (926820705)

Establishment			
Name	Address	ID/FEI	Business Operations
A&Z Pharmaceutical, Inc.		926820705	manufacture(0603-0026), label(0603-0026)

Revised: 2/2013 Qualitest Pharmaceutical, Inc.