ASPIRIN- aspirin tablet, delayed release
America Medic & Science, LLC

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 Delayed Release Tablets USP, 81 MG
Low Dose
Safety Coated Aspirin

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Drug Facts

Active Ingredient

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 release action, this product will not provide fast relief of headaches or other sypmtoms 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 serious illness.

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

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

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 your doctor before use
- 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, kidney disease or asthma
- you are taking a diuretic

Ask your doctor or pharmacist before use if you are taking a prescription drug for
- gout
- diabetes
- arthritis

Stop use and ask doctor if
an allergic reaction occurs. Seek medical help right away.
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 more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a 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 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.

Do not use this product if printed safety seal under cap is torn or missing.

Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

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

- save carton for full directions and warnings
- store at room temperature

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C Yellow # 10 al lake, FD&C Yellow # 6 al lake, methacrylic acid copolymer, microcrystalline cellulose, stearic acid, talc, titanium dioxide, triethyl citrate

Questions or comments?

call 1-855-314-1850

Aspirin Delayed Release Tablets, USP 81 MG

ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49638-115
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49638-115-60	1 in 1 CARTON	07/06/2020	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	07/06/2020	

Labeler - America Medic & Science, LLC (071065464)

Registrant - America Medic & Science, LLC (071065464)

Establishment

Name	Address	ID/FEI	Business Operations
Elvi Pharma LLC		078739246	manufacture(49638-115)

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