ASPIRIN - aspirin tablet Velocity Pharma

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 81mg

Active Ingredient

(in each tablet)

Aspirin 81 mg (NSAID)

Purpose

Pain Relief

Uses

• temporarily relieves minor aches and pains

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
- Asthma (wheezing)
- Shock
- Facial Swelling

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 other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- have 3 or more alcoholic drinks every day while using this product
- takes more or for a longer time than directed

Do not use

• if you have ever had an allergic reaction to any pain reliever or fever reducer.

Ask a doctor before use if:

- The stomach bleeding warning applies to you
- You have 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:

Gout

- Diabetes
- Arthritis

Stop use and ask a doctor if

- you experiences any of the following signs of stomach bleeding:
- feels faint
- vomits blood
- has bloody or black stools
- has stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- New symptoms occur
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs

These could be signs of serious conditions.

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.

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

Directions

Adults and Children 12 years and over:

For temporary relief of minor aches and pains, take 4 to 8 tablets every 4 hours while symptoms persist. Do not exceed 48 tablets in 24 hours unless directed by a doctor.

Children under 12 years of age: Do not use unless directed by a doctor.

Other Information

• Store at a controlled temperature between 62 and 77 degrees F

Inactive Ingredients

Anhydrous Lactose, Carnuba Wax Colloidal Sillicon Dioxide, Crosscarmellose Sodium,FD&C Yellow #10 al lake, FD&C Yellow#6 al Lake, Iron Oxide Ochre, Methacrylic acid copolymer, Micro crystalline cellulose, Polysorbate 80, simethiocone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

Questions?

Call 1-855-314-1850

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by: Velocity Pharma LLC

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Do not use if imprinted safety seal under cap is broken or missing.

Drug Facts

Active ingredient (in each tablet)

Purpose

Aspirin 81mg (NSAID) Pain Relief

Uses:

Temporarily relieves minor aches and pains.

Warnings: Keep outer carton for complete warnings and product information.

- Reye's Syndrome
- Allergy Alert
- Stomach bleeding warning
- Do not use
- Ask a doctor or pharmacist before use
- Stop use and ask a doctor
- Keep out of reach of children

Directions:

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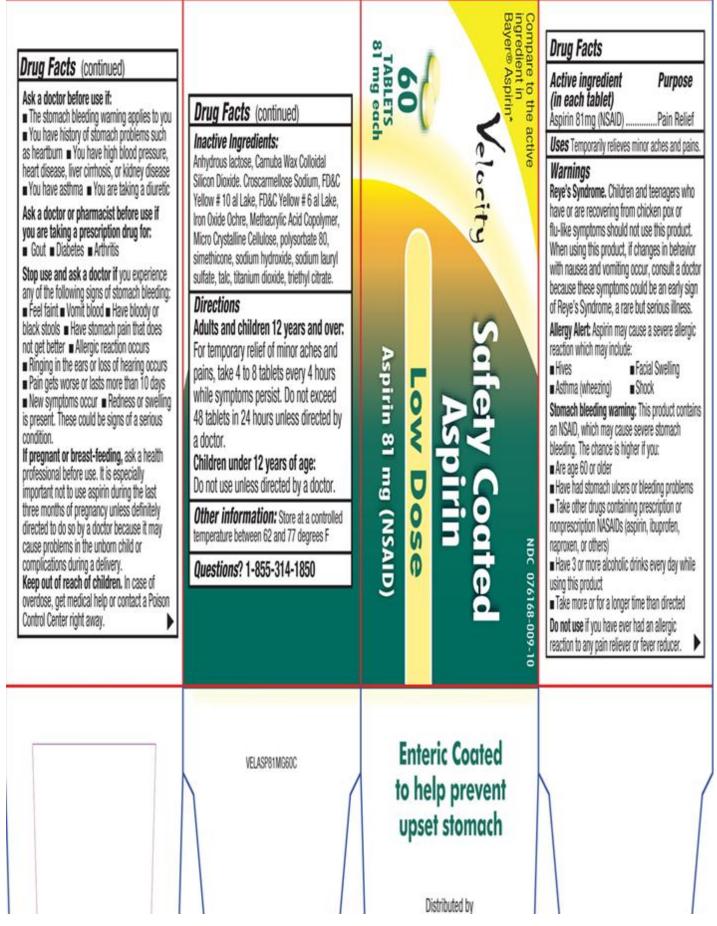
Children under 12 years of age:

Do not use unless directed by a doctor.

Questions? 1-855-314-1850

Distributed by VELOCITY PHARMA LLC 226 B Sherwood Avenue Farmingdale, NY 11735

VELASP81MG60L



NDC: 76168-009-10 -60 COUNT

Enteric Coated to help prevent upset stomach

ASPIRIN

aspirin tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76168-009

Route of Administration ORAL

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

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
ANHYDRO US LACTO SE (UNII: 3S Y5L H9 PMK)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)			
METHACRYLIC ACID (UNII: 1CS02G8656)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			

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

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:76168-009-10	60 in 1 BOTTLE				
1	1 in 1 CARTON				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	0 4/0 1/20 11	

Labeler - Velocity Pharma (962198409)

Registrant - Velocity Pharma (962198409)

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