LOW DOSE ASPIRIN- as pirin tablet, delayed release VALU MERCHANDISERS COMPANY

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.

1080B-BST-2020-0909

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 will not provide fast relief of headaches 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 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 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
- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

- diabetes
- gout
- arthritis

Stop use and ask a 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 for more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

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 (1-800-222-1222).

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 between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Best Choice®

COMPARE TO THE ACTIVE INGREDIENT IN BAYER® LOW DOSE ASPIRIN†

ENTERIC COATED

Low Dose Aspirin

Pain Reliever (NSAID)

Safety Coated / ASPIRIN REGIMEN**

Actual Size

120 COATED TABLETS 81 MG EACH



Active ingredient (in each tablet) Drug Facts

Aspirin 81 mg (NSAID) nonsteroidal anti-infla anti-inflammatory drug Purpose

 other symptoms needing immediate relief.
ask your doctor about other uses for this product for the temporary relief of minor aches and Because of its delayed action, this product will not provide fast relief of headaches or pairs or as recommended by your doctor.

stomach bleeding warning applies to you you have a history of stomach problems, such as

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like

Warnings

his product, if changes in behavior with nausea symptoms should not use this product. When using

and vomiting occur, consult a doctor because

Ask a doctor or pharmacist before use if you are liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma you have high blood pressure, heart disease,

 you experience any of the following signs of stomach bleeding: an allergic reaction occurs. Seek medical help Stop use and ask a doctor if diabetesgoutarthritis taking a prescription drug for:

Stomach bleeding warning: This product contains an NSAID, which may cause severe

are age 60 or older

eaction which may include:

facial swelling

right away.

Illergy alert: Aspirin may cause a severe allergic nese symptoms could be an early sign of Reye's

indrome, a rare but serious illness.

Drug Facts (continued) take other drugs containing prescription or

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer have 3 or more alcoholic drinks every day take more or for a longer time than directed naproxen, or others) while using this product nonprescription NSAIDs (aspirin, ibuprofen,

Ask a doctor before use if

overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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Best Choice®

Actual Size

Pain Reliever (NSAID)

Drug Facts (continued)

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†This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Bayer® Low Dose Aspirin.

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSIN

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EXPIRATION STAMPING INK AND COATING FREE

70038

COMPARE TO THE ACTIVE INGREDIENT IN BAYER® LOW DOSE ASPIRINT

ENTERIC COATED

80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate copolymer, microcrystalline cellulose, polysorbate

Questions or comments?

aluminum lake, iron oxide ochre, methacrylic acid dioxide, croscarmellose sodium, D&C yellow #10 *Inactive ingredients* anhydrous lactose, camauba wax, colloidal silicor

Low Dose Aspirin

120 COATED TABLETS 81 MG EACH

LOW DOSE ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-081
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	ye llo w	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart
Contains			

1	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-081- 01	1 in 1 CARTON	04/01/2020	
1	L	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2020	

Labeler - VALU MERCHANDISERS COMPANY (868703513)

Revised: 9/2020 VALU MERCHANDISERS COMPANY