## LOW DOSE ASPIRIN- as pirin tablet, delayed release DISCOUNT DRUG MART

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-DDM-2020-0806

**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

### PRINCIPAL DISPLAY PANEL

NDC 53943-080-01

DISCOUNT DRUG MART FOOD FAIR

† Compare to the active ingredient in BAYER® LOW DOSE ASPIRIN

Low Dose

**ASPIRIN** 

Pain Reliever(NSAID)

81mg each

Consult your healthcare provider before using this product for your heart.

120 ENTERIC COATED TABLETS



Purpose

have 3 or more alcoholic drinks every day take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, Drug Facts (continued)

while using this product naproxen, or others)

take more or for a longer time than directed

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

# Reye's syndrome: Children and teenagers who Warnings

F DISSATERIER, RETÜRN WÜLEED FORTTON WAD PACKAGEN TO STORE WHERE THEOLAGIS, IT WALKELE TO RETURN TO STORE, SEND REASON FOR DRUG MARTI, 211 COMMERNE DRUG EM PT PACKAGE TO, GROGOUNT DRUG MARTI, 211 COMMERNE DRUG EM PROCHES, OU 44266

Distributed by: Drug Mart - Food Fair 211 Commerce Drive • Medina, OH 44256

16

LOW DOSS

٧,

drug mart

 new symptoms occur These could be signs of a serious condition. ringing in the ears or loss of hearing occurs

take a blood thirming (anticoagulant) or

have had stomach ulcers or bleeding problems

facial swelling

■ shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe asthma (wheezing)

tomach bleeding.

The chance is higher if you:

are age 60 or older

reaction which may include: and vomiting occur, consult a doctor because yndrome, a rare but serious illness

this product, if changes in behavior with nausea symptoms should not use this product. When using have or are recovering from chicken pox or flu-like Allergy alert: Aspirin may cause a severe allergic hese symptoms could be an early sign of Reye's

# an allergic reaction occurs. Seek medical help Stop use and ask a doctor if taking a prescription drug for: ■ gout ■ arthritis

you experience any of the following signs of stomach bleeding: right away.

feel faint

 redness or swelling is present have bloody or black stools
 have stomach pain that does not get better
 pain gets worse or lasts for more than 10 days

> copolymer, microcrystalline cellulose, polysorbate aluminum lake, iron oxide ochre, methacrylic acid anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10

sulfate, starch, talc, fitanium dioxide, triethyl citrate

simethicone, sodium hydroxide, sodium lauryl

# Uses

Aspirin 81 mg (NSAID)\*.....
\* nonsteroidal anti-inflammatory drug for the temporary relief of minor aches and

you have a history of stomach problems, such as Do not use if you are allergic to aspirin or any other Ask a doctor before use if pain reliever/fever reducer stomach bleeding warning applies to you

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

 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 Directions

# Other information children under 12 years: consult a doctor

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

nactive ingredients

in 24 hours unless directed by a doctor

NDC 53943-080-01

† Compare to the active ingredient in BAYER® LOW DOSE ASPIRIN

professional before use. It is especially important not to use aspirin during the last 3 months of

Drug Facts (continued)

f pregnant or breast-feeding, ask a health

Keep out of reach of children. In case of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the

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

Low Dose



Consult your healthcare provider before using this product for your heart.

**120 ENTERIC COATED TABLETS** 

Pain Reliever (NSAID)

## LOW DOSE ASPIRIN

aspirin tablet, delayed release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-080	
Route of Administration	ORAL			

INK AND COATING FREE **EXPIRATION STAMPING** FOR LOT AND

F1080B01DDM R0

0

DO NOT USE IF IMPRINTED S UNDER CAP IS BROKEN OR MI











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

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US LACTO SE (UNII: 3SY5LH9 PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
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)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SODIUM 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					

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-080- 01	1 in 1 CARTON	12/16/2011	
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	NDC:53943-080- 08	3 in 1 CARTON	12/16/2011	
2		120 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:53943-080- 12	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/16/2011	

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/16/2011	

## Labeler - DISCOUNT DRUG MART (047741335)

Revised: 9/2020 DISCOUNT DRUG MART