**ADULT LOW DOSE ASPIRIN- aspirin 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.*

---

**1146-BST-2021-1118**

***Drug Facts***

## Active ingredient (in each tablet)

Aspirin 81 mg (NSAID [1])

---

1 nonsteroidal anti-inflammatory drug

## Purpose

Pain reliever

## 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
- 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 have ever had an allergic reaction to 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:
- gout
- diabetes
- 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; do not exceed 48 tablets in 24 hours
- children under 12 years: do not use unless directed by a doctor

**Other information**

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

**Inactive ingredients**

acetylated monoglycerides, anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, hypromellose phthalate, iron oxide yellow, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polyethylene glycol, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

**PRINCIPAL DISPLAY PANEL**

COMPARE TO THE ACTIVE INGEDIENT IN ST. JOSEPH® LOW DOSE ASPIRIN†

Best Choice®

ADULT LOW DOSE

Aspirin

Actual Size

Pain Reliever (NSAID)

Adult Aspirin Regimen**

Adult Safety Coated

100 ENTERIC COATED TABLETS

81 mg EACH

# ADULT LOW DOSE ASPIRIN

aspirin tablet, delayed release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63941-246 |
| **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 |
|---|---|

| | |
|---|---|
| **DIACETYLATED MONOGLYCERIDES** (UNII: 5Z17386USF) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)** (UNII: 87Y6436BKR) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)** (UNII: 74G4R6TH13) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange (PEACH) | **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:63941-246-03 | 1 in 1 CARTON | 03/27/2017 | |
| **1** | | 100 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 | 03/27/2017 | |

## Labeler - VALU MERCHANDISERS COMPANY (868703513)