**ASPIRIN- aspirin tablet, delayed release**
**GOODSENSE**

*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.*

---

**GDS - 1080B - 2019-0917**

***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**

GOODSENSE®

NDC 50804-880-01

**Aspirin Regimen

Low Dose Safety Coated

Aspirin 81 mg

Actual Size

Pain Reliever (NSAID)

120 ENTERIC COATED TABLETS

Compare to the active ingredient in Bayer® Low Dose Aspirin

100% SATISFACTION GUARANTEED


# ASPIRIN

aspirin tablet, delayed release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50804-880 |
| **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: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **BROWN IRON OXIDE** (UNII: 1N032N7MFO) | |
| **METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)** (UNII: 74G4R6TH13) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **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:50804-880-01 | 1 in 1 CARTON | 01/01/2019 | |
| **1** | | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| **2** | NDC:50804-880-13 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/01/2019 | 05/31/2024 |
| **3** | NDC:50804-880-04 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/10/2021 | |

## Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|---|---|---|---|

| Category | Citation | Date | Date |
|---|---|---|---|
| OTC monograph not final | part343 | 01/01/2019 | |

## Labeler - GOODSENSE (076059836)

Revised: 11/2021 GOODSENSE