

ASPIRIN ENTERIC SAFETY COATED- aspirin tablet

CVS Pharmacy

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.

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 safety coated 81 mg aspirin

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
- shock
- asthma (wheezing)

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
- if you have ever had an allergic reaction to this product or any of its ingredients

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 more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- new symptoms occur

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 (1-800-222-1222) right away.

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 15-30°C (59-86°F)

Inactive ingredients

anhydrous lactose**, black iron oxide**, brown iron oxide**, carnauba wax**, corn starch**, croscarmellose sodium**, D&C yellow #10, FD&C yellow #6**, hypromellose**, methacrylic acid copolymer, microcrystalline cellulose, mineral oil**, pharmaceutical ink**, polysorbate 80**, potassium hydroxide**, propylene glycol**, purified water**, shellac**, silicon

dioxide, simethicone**, sodium bicarbonate**, sodium hydroxide**, sodium lauryl sulfate**, stearic acid**, talc, titanium dioxide, triethyl citrate, yellow iron oxide**

**contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Bayer® Low Dose Aspirin†

Coated Tablets

Low Dose

Aspirin 81 mg

Pain reliever (NSAID)

- Safety coated±
- Aspirin regimen≠

TABLETS

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

±Talk to your doctor or other healthcare provider before using this product for your heart.

±Coating helps protect against stomach upset

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

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

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Product Label

CVS Health. Compare to the active ingredient in Bayer® Low Dose Aspirin!
Coated Tablets
 NDC 69842-826-30

Low Dose Aspirin 81 mg
Pain reliever (NSAID)

- Safety coated†
- Aspirin regimen‡

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81 mg Actual Size

300 TABLETS

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Drug Facts (continued under label)

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CVS Quality
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PEEL HERE

†Coating helps protect against stomach upset

Drug Facts (continued)

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**contains one or more of these ingredients

Questions or comments?
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CVS HEALTH Low Dose Aspirin 81 mg

| ASPIRIN ENTERIC SAFETY COATED | | | |
|---------------------------------|--|--------------------|---------------|
| aspirin tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-826 |
| 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: 3S Y5LH9 PMK) | | |
| | FERROSO FERRIC OXIDE (UNII: XM0 M8 7F357) | | |
| | BROWN IRON OXIDE (UNII: 1N0 32N7MFO) | | |
| | CARNAUBA WAX (UNII: R12CBM0 EIZ) | | |
| | STARCH, CORN (UNII: O8 232NY3SJ) | | |
| | CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |

| |
|--|
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) |
| HYPROMELLOSES (UNII: 3NXW29V3WO) |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |
| MINERAL OIL (UNII: T5L8T28FGP) |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| WATER (UNII: 059QF0KO0R) |
| SHELLAC (UNII: 46N107B71O) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| TALC (UNII: 7SEV7J4R1U) |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------------|
| Color | YELLOW | Score | no score |
| Shape | ROUND | Size | 7mm |
| Flavor | | Imprint Code | E;T8 1;1;Heart |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69842-826-30 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/31/2018 | |
| 2 | NDC:69842-826-50 | 500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/31/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part343 | 08/31/2018 | |

Labeler - CVS Pharmacy (062312574)