

ASPIRIN PAIN RELIVER- aspirin tablet
Pioneer Life Sciences, LLC

Aspirin Pain reliever

Active Ingredient (in each tablet)

Aspirin 81mg (NSAID)

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

PREGNANCY

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

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 at room temperature. Avoid excessive heat above 40°C (104°F).

INACTIVE INGREDIENTS


Microcrystalline Cellulose, Silicon dioxide, Talcum, Cross-carmellose sodium, Steric acid, Colloidal silicon dioxide, Titanium dioxide, Triethyl citrate, Methacrylic acid copolymer, FD&C Yellow #10, FD&C Yellow #6

QUESTIONS OR COMMENTS?

Call **1-732-698-5070** Monday through Friday, 9 am to 5 pm EST.

PRINCIPAL DISPLAY PANEL

Compare to BAYER®
LOW DOSE ASPIRIN
active ingredient.



Aspirin
Low Dose

pain reliever (nsaid)


Safety Coated Aspirin Regimen

Talk to your doctor or other health care provider before using this product for you or heart.

81
mg

500
tablets

not actual size



Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

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 • 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

(continued under label)

*This product is not manufactured or distributed by Bayer Healthcare, LLC owner of the Registered Trademark BAYER® Low Dose Aspirin Tablets Distributed by: **GenCare Consumer Products, LLC** 40E Coakins Ln, Suite A, East Brunswick, NJ 08816

PL0015-00



X002MZOFDJ

Lot No.
Exp. Dt.

PEEL HERE

Drug Facts (continued)

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 • new symptoms occur • ringing in the ears or a loss of hearing occurs

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 at room temperature. Avoid excessive heat above 40°C (104°F).

Other Ingredients: Microcrystalline cellulose, Silicon dioxide, Talcum, Cross-carmellose sodium, Stearic acid, Colloidal silicon dioxide, Titanium dioxide, Triethyl citrate, Methacrylic acid copolymer, D&C Yellow #10, FD&C Yellow #6

Questions or comments? Call **1-732-698-5070** Monday through Friday, 9 am to 5 pm EST.

.5" Glue Area

ASPIRIN PAIN RELIVER

aspirin tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72090-001 |
| 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 |
|--|-----------------|
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| TALC (UNII: 7SEV7J4R1U) | |
| STEARIC ACID D7 (UNII: T3B081197X) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| ACETYLTRIETHYL CITRATE (UNII: 5WBR36T90E) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | yellow | Score | no score |
| Shape | ROUND (Round shape Tablet) | Size | 7mm |
| Flavor | | Imprint Code | 11 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72090-001-01 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M013 | 05/17/2021 | |

Revised: 10/2023

Pioneer Life Sciences, LLC