

ASPIRIN- aspirin tablet, delayed release
INVAHEALTH INC

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Pain reliever

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 problem
- take a blood thinning (anticoagulant) or steroid drug
- take other drug 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

- 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

- 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

- gout
- diabetes
- arthritis

an allergic reaction occurs. Seek medical help right away.

you experience any of the following signs of stomach bleeding:

- feel faint
- have bloody or black stools
- vomit blood
- 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 right away.

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

Call 1-609-642-6380 Monday through Friday 9 am to 5 pm EST

microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, stearic acid, D&C yellow #10, D&C yellow #6 methacrylic acid copolymer, talcum, titanium dioxide, triethyl citrate.

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

In case of overdose, get medical help or contact a Poison Control Center right away.

MedPlus

ASPIRIN

Pain Reliever (NSAID)

ADULT LOW DOSE
81mg each tablet

Safe Pain Relief
 Safety Coated Aspirin Regimen

NDC: 73376-001-50

500 tablets
 not actual size

compare to **BAYER®**
 Low Dose active ingredients

DRUG FACTS

Active ingredient (in each tablet) Aspirin 81 mg (NSAID)
Purpose Nonsteroidal anti-inflammatory drug. Pain reliever.

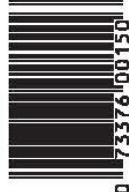
USES: • for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief • ask your doctor about other uses for Bayer Safety Coated 81 mg Aspirin

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 non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or

(continuedumber label)



0 73376-00150-6

MADE IN USA
 Distributed by: InvaHealth Inc
 Cranbury, NJ 08512

TAMPER EVIDENT
 Do not use if safety seal under cap is broken or missing.

Let No. Exp. Dt.
PEEL HERE

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/any other pain reliever/fever reducer • if you have ever had an allergic reaction to this product/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 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/COMMENTS? Call 1-732-688-5070 Monday through Friday, 9 am to 5 pm EST or www.invahealth.com

This product is not manufactured or distributed by Bayer Healthcare, LLC, owner of the Registered Trademark BAYER® Tablets

.5" Glue Area

ASPIRIN

aspirin tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73376-001 |
| 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 |
|---|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ) | |
| TALC (UNII: 7SEV7J4R1U) | |

| | |
|--|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | yellow | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | l1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73376-001-50 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 08/10/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013 | 08/10/2022 | |

Labeler - INVAHEALTH INC (116840615)

Revised: 1/2024

INVAHEALTH INC