

LOW DOSE ASPIRIN- aspirin tablet, coated

Proficient Rx LP

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.

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 have asthma
- you are taking a diuretic

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:
 - o feel faint
 - o vomit blood
 - o have bloody or black stool
 - o have stomach pain that does not get better
- pain gets worse or lasts more than 10 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 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: do not use

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

anhydrous lactose**, black iron oxide**, brown iron oxide**, 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†

Aspirin 81 mg

Low Dose

Pain reliever **(NSAID)**

Aspirin regimen±

Enteric Coated±±

Safety coated

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

≠Coating helps protect against stomach upset

≠Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.

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

Distributed by:

Major® Pharmaceuticals

17177 N Laurel Park Drive,

Suite, Livonia MI 48152

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

Product Label

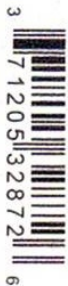


Scan Here



NDC 71205-328-72

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320



Aspirin 81mg

#120 Tablets

Each tablet contains: Aspirin 81 mg (NSAID*) Pain reliever *nonsteroidal anti-inflammatory drug

Yellow, round unscored tablet with imprint code "E T8 1 1"

Product ID: SA032872

Dist. By: Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

Store between 15-30°C (59-86°F)

Keep medication out of the reach of children

Aspirin 81mg
#120 Tablets SN# MASTER
Lot #:00000 Exp:00/00/00
NDC 71205-328-72

Aspirin 81mg
#120 Tablets SN# MASTER
Lot #:00000 Exp:00/00/00
NDC 71205-328-72

Aspirin 81mg
#120 Tablets SN# MASTER
Lot #:00000 Exp:00/00/00
NDC 71205-328-72



GTIN: 00371205328726
SN# MASTER
Exp. 00/00/00
Lot #:00000

Aspirin 81 mg Low Dose

LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-328(NDC:0904-6713) |
| 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: 3S5Y5LH9PMK) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| BROWN IRON OXIDE (UNII: 1N032N7MFO) | |

| |
|----------------------------------------------------------------------------------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) |
| HYPROMELLOSE, UNSPECIFIED (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) |
| STARCH, CORN (UNII: O8232NY3SJ) |
| 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;T81;1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:71205-328-72 | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 09/01/2019 | 02/28/2025 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M013 | 02/28/2018 | 02/28/2025 |

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|----------------------------------------|
| Proficient Rx LP | | 079196022 | REPACK(71205-328) , RELABEL(71205-328) |

Revised: 1/2024

Proficient Rx LP