

ASPIRIN LOW DOSE- aspirin tablet, delayed release
Preferred Pharmaceuticals Inc.

Major 44-600A

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.

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

- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older

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 asthma
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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 vomit blood
 - o have bloody or black stools
 - o feel faint
 - o have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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 at 20 weeks or later in 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

- **do not take more than directed**
- 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 unless directed by a doctor

Other information

- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

(800) 616-2471

Principal Display Panel

Major[®]

Repackaged By: Preferred Pharmaceuticals Inc.

NDC 68788-8334-1

ASPIRIN

Low Dose

PAIN RELIEVER (NSAID)

81 mg

Enteric Coated

Safety Coated

Actual Size

Compare to the active
ingredient in **Bayer[®]**

Low Dose Aspirin†

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

NDC 68788-8334-1

†This product is not manufactured or
distributed by Bayer AG, owner of the
registered trademark Bayer[®] Low Dose
Aspirin. 50844 REV0122A60016

Repackaged By: Preferred Pharmaceuticals Inc.

MAJOR® PHARMACEUTICALS
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152 USA M-17
 Rev. 05/18 Re-order No. 700939

Aspirin 81mg Tab.

Generic for Bayer® Low Dose Aspirin

Each tablet contains: Aspirin 81mg (NSAID)*

... Pain reliever

*nonsteroidal anti-inflammatory drug

Pkg Size: Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Major Pharm.; Livonia, MI

Prod#:

Warning

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). 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. Tablet is round, yellow, and imprinted with



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Aspirin 81mg Tab.
Qty: Ins:
Lot#: Bat#:

Prod# (NDC):

Aspirin 81mg Tab.
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):

Aspirin 81mg Tab.
Qty:
Insurance NDC:
Lot#: Bat#:

Aspirin 81mg Tab.
Qty: Ins:
Lot#: Bat#:
Prod# (NDC):



Directions English

Take ___ tablet(s)
every ___ hours.



Instrucciones Espanol:

Toma ___ tableta(s)
cada ___ horas.

major 44-600A

Log
Chart
Billing
Patient

ASPIRIN LOW DOSE

aspirin tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68788-8334(NDC:0904-6751) |
| 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 |
|--|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| METHACRYLIC ACID (UNII: 1CS02G8656) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SHELLAC (UNII: 46N107B710) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y10) | |
| WATER (UNII: 059QF0KO0R) | |

| | |
|---|--|
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68788-8334-1 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/23/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | 343 | 01/23/2023 | |

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|---------------------|
| Preferred Pharmaceuticals Inc. | | 791119022 | REPACK(68788-8334) |

Revised: 1/2025

Preferred Pharmaceuticals Inc.