

## **ASPIRIN LOW DOSE- aspirin tablet, delayed release**

### **Major Pharmaceuticals**

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**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:
  - vomit blood
  - have bloody or black stools
  - feel faint
  - 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<sup>®</sup>**

NDC 0904-6751-80

**ASPIRIN**

**Low Dose**

**PAIN RELIEVER (NSAID)**

**81 mg**

*Enteric Coated*

*Safety Coated*

Actual Size

**1000 Tablets**

Compare to the active  
ingredient in **Bayer<sup>®</sup>**  
Low Dose Aspirin†

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

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

**MAJOR<sup>®</sup> PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA M-17

Rev. 05/18 Re-order No. 700939

**MAJOR**<sup>®</sup> NDC 0904-6751-80

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Low Dose

**PAIN RELIEVER (NSAID)**  
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Enteric Coated  
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**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

**Sign 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: ■ vomit blood ■ have bloody or black stools ■ feel faint ■ 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

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

**Questions or comments?** (800) 616-2471

Phar. 05/18 Rev. 01/18  
 1717 N. Central Expressway, Suite 203  
 M-17  
 48125 USA  
 MAJOR PHARM, INC.  
 1000 PHARMACIST DRIVE  
 ASPRIN 81MG 1000 TABLETS  
 NDC 0904-6751-80  
 The product is not manufactured or distributed by Bayer AG, owner of the Bayer logo.

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major 44-600A

| ASPIRIN LOW DOSE                                       |                   |                    |               |
|--|-------------------|--------------------|---------------|
| aspirin tablet, delayed release                        |                   |                    |               |
| Product Information                                    |                   |                    |               |
| Product Type   | HUMAN OTC DRUG    | Item Code (Source) | 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: 3WQ0SDWL1A)    |                   |                    |               |
| SHELLAC (UNII: 46N107B710)                             |                   |                    |               |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                     |                   |                    |               |
| DIMETHICONE (UNII: 92RU3N3Y1O)                         |                   |                    |               |
| 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

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

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0904-6751-80 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2011           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 05/01/2011           |                    |

**Labeler** - Major Pharmaceuticals (191427277)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867837 | manufacture(0904-6751) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(0904-6751) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations                      |
|-------------------------|---------|-----------|--|
| LNK International, Inc. |         | 868734088 | manufacture(0904-6751) , pack(0904-6751) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 117025878 | manufacture(0904-6751) |