

**ASPIRIN - aspirin tablet, delayed release**  
**Sunrise Pharmaceutical Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Unknown Title**

**OTC - ACTIVE INGREDIENT**

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**OTC - PURPOSE**

Pain reliever

**INDICATIONS AND USAGE**

- for the temporary relief of minor aches and pains or as recommended by your doctor.  
**Because of its delayed release 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
- 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 everyday while using this product
- take more or for a longer time than directed

**OTC - DO NOT USE**

If you are allergic to aspirin or any other pain reliever/fever reducer.

**OTC - 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

### **OTC - ASK A DOCTOR/PHARMACIST BEFORE USE IF YOU ARE**

taking a prescription drug for:

- Gout
- Diabetes
- arthritis

### **OTC - STOP USE AND ASK A DOCTOR IF**

- 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
- allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

### **OTC - 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.**

### **OTC - KEEP OUT OF REACH OF CHILDREN**

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

### **DOSAGE AND ADMINISTRATION**

- 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 15°-30°C (59°-86°F)
- do not use if seal on the carton is missing or damaged

### **INACTIVE INGREDIENT**

colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polyethylene glycol, propylene glycol, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin, triethyl

citrate.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 11534-073-11  
 \*\*Compare to active ingredient in Bayer® Low Dose

**Aspirin 81 mg**  
 See new warnings information  
 Pain Reliever Adult Low Dose



Enteric Coated  
 Pain Reliever (NSAID) 120 Tablets

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 495 East Lincoln Ave.  
 Rahway, NJ 07065

Manufactured by:  
 Sunrise Pharmaceutical, Inc.  
 Rahway, NJ 07065 USA  
 www.sunrisepharma.com

|   |                                 |
|---|---------------------------------|
| <b>Drug Facts</b><br><b>Active ingredient</b><br>(in each tablet)<br>Aspirin 81 mg (NSAID)* ..... Pain reliever<br>*nonsteroidal anti-inflammatory drug   | <b>Purpose</b><br>Pain reliever |
| <b>Uses</b><br>■ for the temporary relief of minor aches and pains or as recommended by your doctor.<br><b>Because of its delayed release action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.</b>  |                                 |
| <b>Warnings</b><br><b>Reye's syndrome:</b> 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.<br><b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock<br><b>Stomach bleeding warning:</b> 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 |                                 |

**Drug Facts** (continued on Back of Label) REV 11/2010  
 \*\*Sunrise Pharmaceutical, Inc. is not affiliated with the owner of the trademark Bayer® Low Dose



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**No Varnish**

PEEL HERE

|  |  |
|--|--|
| <b>Drug Facts (Continued)</b><br>alcoholic drinks every day while using this product<br>■ take more or for a longer time than directed<br><b>Do not use</b> if you are allergic to aspirin or any other pain reliever/fever reducer.<br><b>Ask a doctor before use if</b> ■ 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<br><b>Ask a doctor or pharmacist before use if you</b> are taking a prescription drug for ■ gout ■ diabetes ■ arthritis<br><b>Stop use and ask a doctor if</b><br>■ you experience any of the following signs of stomach bleeding:<br>■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better<br>■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present<br>■ new symptoms occur<br>■ ringing in the ears or loss of hearing occurs<br>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.<br>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. | <b>Directions</b><br>■ drink a full glass of water with each dose<br>■ 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<br>■ children under 12 years: consult a doctor  |
| <b>Other information</b> ■ store at 15°-30°C (59°-86°F) ■ do not use if imprinted seal under cap is missing or damaged.  | <b>Inactive ingredients</b> colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polyethylene glycol, propylene glycol, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate |

|  |                          |                           |
|--|--------------------------|---------------------------|
| <b>ASPIRIN</b>   |                          |                           |
| aspirin tablet, delayed release                        |                          |                           |
| <b>Product Information</b>                             |                          |                           |
| <b>Product Type</b>                                    | HUMAN OTC DRUG           | <b>Item Code (Source)</b> |
| <b>Route of Administration</b>                         | ORAL                     | NDC:11534-073             |
| <b>Active Ingredient/Active Moiety</b>                 |                          |                           |
| <b>Ingredient Name</b>                                 | <b>Basis of Strength</b> | <b>Strength</b>           |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN                  | 81 mg                     |
| <b>Inactive Ingredients</b>                            |                          |                           |

| Ingredient Name   | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)  |          |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)  |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)  |          |
| HYPROMELLOSE 2208 (100 MPAS) (UNII: B1QE5P712K)                             |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)                              |          |
| MINERAL OIL (UNII: T5L8T28FGP)  |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)                                     |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)   |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)   |          |
| TALC (UNII: 7SEV7J4R1U)   |          |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)                                    |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)   |          |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO)                                       |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                                    |          |
| TRIACETIN (UNII: XHX3C3X673)  |          |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM)   |          |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) |          |

### Product Characteristics

|          |        |              |          |
|----------|--------|--------------|----------|
| Color    | YELLOW | Score        | no score |
| Shape    | ROUND  | Size         | 7mm      |
| Flavor   |        | Imprint Code | SP;03    |
| Contains |        |              |          |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:11534-073-11 | 120 in 1 BOTTLE                                  |                      |                    |
| 2 | NDC:11534-073-05 | 57603 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part343                                  | 12/26/2005           |                    |

**Labeler** - Sunrise Pharmaceutical Inc (168522378)

Revised: 8/2013

Sunrise Pharmaceutical Inc