

**ASPIRIN LOW DOSE- aspirin tablet, delayed release**  
**Rugby Laboratories**

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**Rugby 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
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product

**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**

- you have asthma
- stomach bleeding warning applies to you
- 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
- 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

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***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***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?***

**1-800-645-2158**

### ***Principal Display Panel***

**Rugby®**

NDC 0536-1234-41

Compare to the active ingredient  
in Bayer® Low Dose Aspirin†

Talk to your doctor or other  
healthcare provider before using  
this product for your heart.

Low Dose

**Aspirin 81 mg**

Pain Reliever (**NSAID**)

Aspirin Regimen

**120** Enteric Coated Tablets

**Safety Coated**

Actual Size

†This product is not manufactured or distributed by Bayer  
AG, owner of the registered trademark Bayer® Low Dose  
Aspirin. 50844 REV0122A60032

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

Rev. 05/19 R-17 Re-order No. 370718



### Rugby 44-600A

## ASPIRIN LOW DOSE

aspirin tablet, delayed release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0536-1234 |
| <b>Route of Administration</b> | 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 (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:0536-1234-41 | 1 in 1 CARTON   | 07/01/2019           |                    |
| 1 |                  | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 07/01/2019           |                    |

**Labeler** - Rugby Laboratories (079246066)

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867837 | manufacture(0536-1234) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(0536-1234) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations                      |
|-------------------------|---------|-----------|--|
| LNK International, Inc. |         | 868734088 | manufacture(0536-1234) , pack(0536-1234) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 117025878 | manufacture(0536-1234) |

Revised: 4/2025

Rugby Laboratories