

**ASPIRIN LOW DOSE- aspirin tablet, delayed release**  
**L.N.K. International, Inc.**

-----  
**Quality Plus 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

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

**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 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:
  - 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?***

**1-800-426-9391**

### ***Principal display panel***

**Quality  
+Plus**

NDC 50844-600-32

†Compare to active ingredient in  
Bayer® Low Dose Aspirin

**LOW DOSE  
ASPIRIN 81 mg  
PAIN RELIEVER  
(NSAID)**

- **ASPIRIN REGIMEN**
- **SAFETY COATED**

**120  
ENTERIC Coated Tablets**

### **ACTUAL SIZE**

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

**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®  
Low Dose Aspirin. 50844 REV0122D60032

Distributed by **LNK INTERNATIONAL, INC.**  
60 Arkay Drive, Hauppauge, NY 11788  
USA

**Lot no. & Exp. Date**

0150844 56332 2

**QUALITY PLUS**

LOW DOSE

# ASPIRIN 81 mg

PAIN RELIEVER (NSAID)

120

ENTERIC Coated Tablets

ACTUAL SIZE

• ASPIRIN REGIMEN  
• SAFETY COATED

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

**Drug Facts (continued)**

polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?**  
1-800-426-9391

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60 Arkay Drive, Hauppauge, NY 11788 USA

**Quality Plus 44-600A**

**Drug Facts (continued)**

■ pain gets worse or lasts more than 10 days  
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■ 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.  
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NDC 50844-600-32

\*Compare to active ingredient in Bayer® Low Dose Aspirin

**Drug Facts (continued)**

■ have had stomach ulcers or bleeding problems while using this product  
■ have 3 or more alcoholic drinks every day  
■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

**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 as heartburn  
■ 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: ■ vomit blood ■ feel faint ■ have bloody or black stools ■ have stomach pain that does not get better ■ ringing in the ears or a loss of hearing occurs

**Drug Facts (continued)**

**Active ingredient (in each tablet)**  
Aspirin 81 mg (NSAID)\*, nonsteroidal anti-inflammatory drug

**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.  
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**Drug Facts (continued)**

polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?**  
1-800-426-9391

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60 Arkay Drive, Hauppauge, NY 11788 USA

**Quality Plus 44-600A**

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## ASPIRIN LOW DOSE

aspirin tablet, delayed release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50844-600 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN           | 81 mg    |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                     |          |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 355W5USQ3G)            |          |
| <b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)            |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)        |          |
| <b>METHACRYLIC ACID</b> (UNII: 1CS02G8656)                 |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)       |          |
| <b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)                     |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A) |          |
| <b>SHELLAC</b> (UNII: 46N107B71O)                          |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                      |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |          |
| <b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)               |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)            |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                             |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                 |          |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)                        |          |
| <b>TRIETHYL CITRATE</b> (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:50844-600-32 | 1 in 1 BOX  | 05/01/2011           |                    |
| 1 |                  | 120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:50844-600-95 | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/01/2011           |                    |
| 3 | NDC:50844-600-17 | 1 in 1 BOX  | 05/01/2011           | 12/18/2020         |
| 3 |                  | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |
| 4 | NDC:50844-600-01 | 1 in 1 BOX  | 05/01/2011           | 12/18/2020         |
| 4 |                  | 30 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                                     | 05/01/2011           |                    |

**Labeler** - L.N.K. International, Inc. (038154464)

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867837 | manufacture(50844-600) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(50844-600) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations                      |
|-------------------------|---------|-----------|--|
| LNK International, Inc. |         | 868734088 | manufacture(50844-600) , pack(50844-600) |

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 117025878 | manufacture(50844-600) |

Revised: 6/2023

L.N.K. International, Inc.