

**ASPIRIN- aspirin tablet, delayed release**  
**Topco Associates, LLC**

-----  
**TopCare 44-645**

***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 a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- are age 60 or older
- 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**

- you are taking a diuretic
- 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

**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°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

## ***Inactive ingredients***

colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

## ***Questions or comments?***

**1-888-423-0139**

## ***Principal Display Panel***

NDC 36800-545-60

**TopCare  
health®**

COMPARE TO ST. JOSEPH® LOW DOSE SAFETY  
COATED 81 mg ASPIRIN ACTIVE INGREDIENT†

LOW DOSE ♥ ASPIRIN REGIMEN\*\*

**Aspirin 81 mg**  
**PAIN RELIEVER (NSAID)**

Safety Coated

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

actual size

## **180 ENTERIC COATED TABLETS**

†This product is not manufactured or distributed by Foundation  
Consumer Healthcare, LLC, owner of the registered trademark  
St. Joseph® Low Dose Safety Coated 81 mg Aspirin.  
50844 REV0122A64560

DISTRIBUTED BY  
TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
©TOPCO LNKA1220  
QUESTIONS? 1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com

This TopCare® product is laboratory  
tested to guarantee its highest quality.  
Your total satisfaction is guaranteed.

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED**

# SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

No Varnish/No Print  
Lot # & Expiry Area


NDC 36800-545-60

COMPARE TO ST. JOSEPH® LOW DOSE SAFETY COATED 81 mg ASPIRIN ACTIVE INGREDIENT!

**LOW DOSE** ♥ **ASPIRIN REGIMEN\*\***

## Aspirin 81 mg

**PAIN RELIEVER (NSAID)** \*Talk to your doctor or other healthcare provider before using this product for your heart.

**Safety Coated**

**180 ENTERIC COATED TABLETS**
actual size


NDC 36800-545-60

COMPARE TO ST. JOSEPH® LOW DOSE SAFETY COATED 81 mg ASPIRIN ACTIVE INGREDIENT!

**LOW DOSE** ♥ **ASPIRIN REGIMEN\*\***

## Aspirin 81 mg

**PAIN RELIEVER (NSAID)** \*Talk to your doctor or other healthcare provider before using this product for your heart.

**Safety Coated**

**180 ENTERIC COATED TABLETS**
actual size

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



0 36800 10953 7

Scan here for more information or call 1-888-423-0139



**QUESTIONS OR COMMENTS?** 1-888-423-0139

**QUESTIONS OR COMMENTS?** 1-888-423-0139

B-1910-645-60-R  
REV0122A64560

**Drug Facts (continued)**

**Ask a doctor or pharmacist before you start 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
- you get worse or feel more than 3 days
- before 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** colloidal amylose, silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, stannous chloride, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?** 1-888-423-0139

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**

**Active ingredient (in each tablet)** Aspirin 81 mg (NSAID)\*

**Other ingredients** 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.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- facial swelling
- hives
- shock
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take more or for a longer time than directed
- 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**

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

Topcare 44-645

## ASPIRIN

aspirin tablet, delayed release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:36800-545 |
| <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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                     |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)              |          |
| <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>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>    | pink  | <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:36800-545-60 | 1 in 1 CARTON   | 03/19/2021           |                    |
| 1 |                  | 180 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                                     | 03/19/2021           |                    |

**Labeler** - Topco Associates, LLC (006935977)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. |         | 038154464 | pack(36800-545)     |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867837 | manufacture(36800-545) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(36800-545) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 868734088 | manufacture(36800-545) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. |         | 967626305 | pack(36800-545)     |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. |         | 117025878 | manufacture(36800-545) |

Revised: 3/2025

Topco Associates, LLC