

**ASPIRIN- aspirin tablet, coated**  
**Advanced Rx Pharmacy of Tennessee, LLC**

*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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**Aspirin 325g Tablet**

**Active Ingredient (in each tablet)**

Aspirin 325 mg(NSAID)\*

\*nonsteroidal anti-inflammatory drug

Pain reliever

temporarily relieves minor aches and pains due to:

headache

muscle pain

toothache

menstrual pain

colds

minor pains of arthritis

temporarily reduces fever

**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 every day while using this product
- take more or for a longer time than directed

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- taking a prescription drug for diabetes, gout or arthritis

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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

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.

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

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours while symptoms last. Do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

**Directions**

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 1-2 tablets every 4 hours, as needed, not more than 12 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

## Other Information

store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F)

black iron oxide, cellulose, corn starch, D&C yellow #10 lake, FD&C yellow #6 lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, silicon dioxide, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate.

Manufacturer: 1-800-540-3765

### Other information

store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)  
use by expiration date on package

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs

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|--|--|
| <p>Packed By:<br/><b>AdvancedRx</b><br/>NashvilleTN, 37217</p>  <p>Store at 20°-25°C (68°-77°F)<br/>Caution: Federal law PROHIBITS Transfer of this drug to any person other than the patient for whom it was prescribed.</p> | <p>Packed By:<br/><b>AdvancedRx</b><br/>NashvilleTN, 37217</p>  <p>Store at 20°-25°C (68°-77°F)<br/>Caution: Federal law PROHIBITS Transfer of this drug to any person other than the patient for whom it was prescribed.</p> |
| <p><b>ASPIRIN EC 325MG TABLET</b></p> <p>#30</p> <p>Compare to ECOTRIN<br/>NDC: 80425-0293-01 Source NDC: 57896-0921-01<br/>Lot: 30ASP325924 Expires: 9/30/2024</p>   | <p><b>ASPIRIN EC 325MG TABLET</b></p> <p>#60</p> <p>Compare to ECOTRIN<br/>NDC: 80425-0293-02 Source NDC: 57896-0921-01<br/>Lot: XXXXXXXX Expires: 9/30/2024</p>    |
| <p>ASPIRIN EC 325MG TABLET #30<br/>NDC: 80425-0293-01<br/>Source NDC: 57896-0921-01<br/>Lot: 30ASP325924 Exp:9/30/2024</p> <p>GERI-CARE<br/>S/N: 000000137267</p>  | <p>ASPIRIN EC 325MG TABLET #60<br/>NDC: 80425-0293-02<br/>Source NDC: 57896-0921-01<br/>Lot: XXXXXXXX Exp:9/30/2024</p> <p>GERI-CARE<br/>S/N: 000000137273</p>   |
| <p>Packed By:<br/><b>AdvancedRx</b><br/>NashvilleTN, 37217</p>  <p>Store at 20°-25°C (68°-77°F)<br/>Caution: Federal law PROHIBITS Transfer of this drug to any person other than the patient for whom it was prescribed.</p> |  |
| <p><b>ASPIRIN EC 325MG TABLET</b></p> <p>#90</p> <p>Compare to ECOTRIN<br/>NDC: 80425-0293-03 Source NDC: 57896-0921-01<br/>Lot: XXXXXXXXXXXX Expires: 9/30/2024</p>    |  |
| <p>ASPIRIN EC 325MG TABLET #90<br/>NDC: 80425-0293-03<br/>Source NDC: 57896-0921-01<br/>Lot: XXXXXXXXXXXX Exp:9/30/2024</p> <p>GERI-CARE<br/>S/N: 000000137274</p>   |  |

# ASPIRIN

aspirin tablet, coated

## Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:80425-0293(NDC:57896-921) |
| <b>Route of Administration</b> | ORAL           |                           |                               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN           | 325 mg   |

## Inactive Ingredients

| Ingredient Name                                | Strength |
|--|----------|
| FERROSO FERRIC OXIDE (UNII: XM0M87F357)        |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |          |

## Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | orange | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 9mm      |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | 44;227   |
| <b>Contains</b> |        |                     |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:80425-0293-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |
| 2 | NDC:80425-0293-2 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |
| 3 | NDC:80425-0293-3 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 04/27/2023           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 04/27/2023           |                    |

**Labeler** - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

## Establishment

| Name                                   | Address | ID/FEI    | Business Operations |
|--|---------|-----------|---------------------|
| Advanced Rx Pharmacy of Tennessee, LLC |         | 117023142 | repack(80425-0293)  |

Revised: 4/2023

Advanced Rx Pharmacy of Tennessee, LLC