ASPIRIN LOW DOSE - aspirin tablet, coated
Quality Care Products, 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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Major 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 other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take more or for a longer time than directed
- 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
- stomach bleeding warning applies to you
- you have asthma
- 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
- 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 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 (1-800-222-1222) right away.

**Directions**
- 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**
- use by expiration date on package
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)

**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
# ASPIRIN LOW DOSE

aspirin tablet, coated

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:55700-842(NDC:0904-6751)</th>
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<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)</td>
<td>ASPIRIN</td>
<td>81 mg</td>
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## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>STARCH, CORN (UNII: O8232NY3SJ)</td>
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<tr>
<td>D&amp;C YELLOW NO. 10 (UNII: 35SW5USQ3G)</td>
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<tr>
<td>FD&amp;C Yellow NO. 6 (UNII: H77VEB3A8)</td>
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<tr>
<td>HYPROMELLOSES (UNII: 3NXW29V3WO)</td>
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<tr>
<td>METHACRYLIC ACID (UNII: 1CS02G8656)</td>
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<td>MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)</td>
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<td>POLYDEXTROSE (UNII: VH2XOU12IE)</td>
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<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
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<td>SHELLAC (UNII: 46NI07B71O)</td>
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<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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<td>SODIUM BICARBONATE (UNII: 8MDF5V39QO)</td>
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<td>SODIUM LAURYL SULFATE (UNII: 368GB5141J)</td>
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### Product Characteristics

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<tr>
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### Packaging

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<td>NDC:55700-842-30</td>
<td>30 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<td>OTC MONOGRAPH NOT FINAL</td>
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<td>02/07/2020</td>
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### Labeler

- Quality Care Products, LLC (831276758)

### Establishment

<table>
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<tr>
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<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<td>Quality Care Products, LLC</td>
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<td>831276758</td>
<td>repack(55700-842)</td>
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Revised: 2/2020