HIGHLIGHTS OF PRESCRIBING INFORMATION

ASPIRIN (FORMULATION) (acetylsalicylic acid)

PROFESSIONAL INDICATIONS AND USAGE

Vascular Indications:
- Ischemic Strokes and Transient Ischemic Attacks (TIA)
- Suspected Acute Myocardial Infarction (MI)
- Prevention of Recurrent MI
- Unstable Angina Pectoris
- Chronic Stable Angina Pectoris
- Revascularization Procedures in Select Patients:
  - Coronary Artery Bypass Graft (CABG)
  - Percutaneous Transluminal Coronary Angioplasty (PTCA)
  - Carotid Endarterectomy

Rheumatologic Disease Indications:
- Rheumatoid Arthritis
- Juvenile Rheumatoid Arthritis
- Spondyloarthropathies
- Osteoarthritis
- Arthritis and Pleurisy of Systemic Lupus Erythematosus (SLE)

Dosage and Administration

General: Each dose should be taken with a full glass of water unless contraindicated. Doses may need to be individualized depending on indication.

<table>
<thead>
<tr>
<th>Indications</th>
<th>Recommended Daily Dose</th>
<th>Duration of Therapy</th>
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<tbody>
<tr>
<td>Vascular Indications:</td>
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<tr>
<td>Ischemic Strokes and TIA</td>
<td>50-325 milligrams (mg) daily</td>
<td>Indefinitely</td>
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<tr>
<td>Suspected Acute MI</td>
<td>160-162.5 mg taken as soon as infarction is suspected, then once daily</td>
<td>For 30 days post infarction (after 30 days consider further treatment based on indication for previous MI)</td>
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<tr>
<td>Prevention of Recurrent MI</td>
<td>75-325 mg daily</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Unstable Angina Pectoris</td>
<td>75-325 mg daily</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Chronic Stable Angina Pectoris</td>
<td>75-325 mg daily</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Revascularization Procedures in Select Patients:</td>
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<tr>
<td>CABG</td>
<td>325 mg daily starting 6 hrs postprocedure Maintenance therapy 160-325 mg daily</td>
<td>1 year</td>
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<tr>
<td>PTCA</td>
<td>325 mg 2 hours presurgery</td>
<td>Indefinitely</td>
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<td></td>
<td>Maintenance therapy 160-325 mg daily</td>
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<tr>
<td>Carotid Endarterectomy</td>
<td>80 mg daily to 650 mg twice a day started presurgery</td>
<td>Indefinitely</td>
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</table>

Rheumatologic Disease Indications:
- Rheumatoid Arthritis
  - Initial dose 3 g daily. Target plasma salicylate levels 150-300 micrograms/millilitre (μg/mL)
  - As indicated
- Juvenile Rheumatoid Arthritis
  - Initial dose 90-130 mg/kg/days. Target plasma salicylate levels 150-300 μg/mL
  - As indicated
- Spondyloarthropathies
  - Up to 4 grams (g) daily
  - As indicated
- Osteoarthritis
  - Up to 3 g daily
  - As indicated
- Arthritis and Pleurisy of SLE
  - Initial dose 3 g daily. Target plasma salicylate levels 150-300 μg/mL
  - As indicated

CONTRAINDICATIONS

Aspirin is contraindicated in patients with known allergy to nonsteroidal anti-inflammatory drugs and in patients with the syndrome of asthma, rhinitis, and nasal polyps. Aspirin should not be used in children or teenagers for viral infections, with or without fever, because of the risk of Reye's syndrome with concomitant use of aspirin in certain viral illnesses.

PRECAUTIONS

General
- Renal Failure
- Hepatic Insufficiency
- Sodium Restricted Diets

Laboratory Tests
- Drug Interactions
  - Angiotensin Converting Enzyme (ACE) Inhibitors
  - Acetazolamide
  - Anticoagulant Therapy
  - Anticonvulsants
  - Beta Blockers
  - Diuretics
  - Methylxanate
  - Nonsteroidal Anti-inflammatory Drugs (NSAID's)
  - Oral Hypoglycemics
  - Uricosuric Agents
  - Carcinogenesis, Mutagenesis, Impairment of Fertility
  - Pregnancy, Labor and Delivery, Nursing Mothers

Pediatric Use

WARNINGS
- Alcohol Warning
- Coagulation Abnormalities
- Gastrointestinal Side Effects
- Pestic Ulcer Disease

ADVERSE REACTIONS (Most common)
- Gastritis (Abdominal Pain, Ulceration, Bleeding)
- Inhibition of Platelet Aggregation (Bleeding)
- Tinnitus
- Dizziness
- Hearing Loss

To report SERIOUS adverse drug reactions, call (manufacturer) at (phone number) or MEDWATCH at 1-800-FDA-1088

HOW SUPPLIED

(insert specific information regarding, strength of dosage form, units in which the dosage form is generally available, and information to facilitate identification of the dosage form.) Store in a tight container at 25°C (77 °F); exceptions permitted to 15-30°C (59-86 °F).

These highlights do not include all the information needed to prescribe aspirin safely and effectively. See aspirin's comprehensive prescribing information.