

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:¹

- 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)

Warnings Regarding Use in Pregnancy

Pregnant women should only take aspirin if clearly needed. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of the ductus arteriosus), use during the third trimester of pregnancy should be avoided. Salicylate products have also been associated with alterations in maternal and neonatal hemostasis mechanisms, decreased birth weight, and with perinatal mortality. Salicylate is excreted in breast milk. (See "Pregnancy," "Labor and Delivery" and "Nursing Mothers" in the "Precautions" section of the Comprehensive Prescribing Information.)

¹Patients with a pre-existing condition for which aspirin is already indicated. See "Revascularization Procedures" under the "Indications and Usage" and "Clinical Studies" sections in the Comprehensive Prescribing Information.

..... 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.

Indications	Recommended Daily Dose	Duration of Therapy
Vascular Indications:		
Ischemic Strokes and TIA	50-325 milligrams (mg) daily	Indefinitely
Suspected Acute MI	160-162.5 mg taken as soon as infarction is suspected; then once daily	For 30 days post infarction (after 30 days consider further treatment based on indication for previous MI)
Prevention of Recurrent MI	75-325 mg daily	Indefinitely
Unstable Angina Pectoris	75-325 mg daily	Indefinitely
Chronic Stable Angina Pectoris	75-325 mg daily	Indefinitely
Revascularization Procedures in Select Patients:		
CABG	325 mg daily starting 6 hrs. postprocedure	1 year
PTCA	325 mg 2 hours presurgery Maintenance therapy: 160-325 mg daily	Indefinitely
Carotid Endarterectomy	80 mg daily to 650 mg twice a day started presurgery	Indefinitely
Rheumatologic Disease Indications:		
Rheumatoid Arthritis	Initial dose 3 g daily. Target plasma salicylate levels 150-300 micrograms/milliliter ($\mu\text{g/mL}$)	As indicated
Juvenile Rheumatoid Arthritis	Initial dose 90-130 mg/kg/day. Target plasma salicylate levels 150-300 $\mu\text{g/mL}$	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 $\mu\text{g/mL}$	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
- Methotrexate
- 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
- Peptic Ulcer Disease

ADVERSE REACTIONS (Most common)

- Gastrointestinal (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); excursions 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.