

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 (µg/mL) | As indicated |
| Juvenile Rheumatoid Arthritis | Initial dose 90-130 mg/kg/day. 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
 - 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 light 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.

(b) [Reserved]

[63 FR 56814, Oct. 23, 1998; 63 FR 66015, 66016, Dec. 1, 1998, as amended at 64 FR 49653, Sept. 14, 1999]

Subpart D—Testing Procedures

§ 343.90 Dissolution and drug release testing.

(a) [Reserved]

(b) *Aspirin capsules*. Aspirin capsules must meet the dissolution standard for aspirin capsules as contained in the United States Pharmacopeia (USP) 23 at page 132.

(c) *Aspirin delayed-release capsules and aspirin delayed-release tablets*. Aspirin delayed-release capsules and aspirin delayed-release tablets must meet the drug release standard for aspirin delayed-release capsules and aspirin delayed-release tablets as contained in USP 23 at pages 133 and 136 respectively.

(d) *Aspirin tablets*. Aspirin tablets must meet the dissolution standard for aspirin tablets as contained in USP 23 at page 134.

(e) *Aspirin, alumina, and magnesia tablets*. Aspirin in combination with alumina and magnesia in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesia tablets as contained in USP 23 at page 138.

(f) *Aspirin, alumina, and magnesium oxide tablets*. Aspirin in combination with alumina, and magnesium oxide in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesium tablets as contained in USP 23 at page 139.

(g) *Aspirin effervescent tablets for oral solution*. Aspirin effervescent tablets for oral solution must meet the dissolution standard for aspirin effervescent tablets for oral solution as contained in USP 23 at page 137.

(h) *Buffered aspirin tablets*. Buffered aspirin tablets must meet the dissolution standard for buffered aspirin tablets as contained in USP 23 at page 135.

PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

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344.1 Scope.
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Subpart B—Active Ingredients

- 344.10 Earwax removal aid active ingredient.
344.12 Ear drying aid active ingredient.

Subpart C—Labeling

- 344.50 Labeling of earwax removal aid drug products.
344.52 Labeling of ear drying aid drug products.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 51 FR 28660, Aug. 8, 1986, unless otherwise noted:

Subpart A—General Provisions

§ 344.1 Scope.

(a) An over-the-counter topical otic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 344.3 Definitions.

As used in this part:

(a) *Anhydrous glycerin*. An ingredient that may be prepared by heating glycerin U.S.P. at 150° C for 2 hours to drive off the moisture content.

(b) *Earwax removal aid*. A drug used in the external ear canal that aids in the removal of excessive earwax.

(c) *Water-clogged ears*. The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) *Ear drying aid*. A drug used in the external ear canal to help dry water-clogged ears.

[51 FR 28660, Aug. 8, 1986, as amended at 65 FR 48905, Aug. 10, 2000]

Subpart B—Active Ingredients

§ 344.10 Earwax removal aid active ingredient.

The active ingredient of the product consists of carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

[51 FR 28660, Aug. 8, 1986, as amended at 65 FR 48905, Aug. 10, 2000]