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Aspirin

Drug Information Provided by Lexi-Comp

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Special Alerts

McNeil Consumer Healthcare OTC Products: Voluntary Recall - January 2010

McNeil Consumer Healthcare has expanded a previous recall to include specific lots of certain additional OTC products. For information on returning the recalled products, contact McNeil Consumer Healthcare at (800) 222-6036.

For additional information and a link to the full list of recalled products and lot numbers, please refer to <http://www.fda.gov/Safety/Recalls/ucm197746.htm>.

Medication Safety Issues

Sound-alike/look-alike issues:

Aspirin may be confused with Afrin®, Asendin®

Ascriptin® may be confused with Aricept®

Ecotrin® may be confused with Akineton®, Edecrin®, Epogen®

Halfprin® may be confused with Halfan®, Haltran®

ZORprin® may be confused with Zyloprim®

International issues:

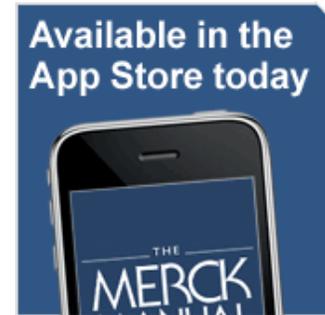
Cartia® [multiple international markets] may be confused with Cartia XT® which is a brand name for diltiazem in the U.S.

Pronunciation

(AS pir in)

U.S. Brand Names

- Ascriptin® Maximum Strength [OTC]
- Ascriptin® [OTC]
- Aspercin [OTC]
- Aspergum® [OTC]
- Aspirtab [OTC]



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- Bayer® Aspirin Extra Strength [OTC]
- Bayer® Aspirin Regimen Adult Low Dose [OTC]
- Bayer® Aspirin Regimen Children's [OTC]
- Bayer® Aspirin Regimen Regular Strength [OTC]
- Bayer® Genuine Aspirin [OTC]
- Bayer® Plus Extra Strength [OTC]
- Bayer® with Heart Advantage [OTC] [DSC]
- Bayer® Women's Aspirin Plus Calcium [OTC] [DSC]
- Bayer® Women's Low Dose Aspirin [OTC]
- Buffasal [OTC]
- Bufferin® Extra Strength [OTC]
- Bufferin® [OTC]
- Buffinol [OTC]
- Easprin®
- Ecotrin® Low Strength [OTC]
- Ecotrin® Maximum Strength [OTC]
- Ecotrin® [OTC]
- Genacote™ [OTC]
- Halfprin® [OTC]
- St. Joseph® Adult Aspirin [OTC]
- ZORprin®

Index Terms

- Acetylsalicylic Acid
- ASA
- Baby Aspirin

Generic Available

Yes: Excludes gum

Canadian Brand Names

- Asaphen
- Asaphen E.C.
- Entrophen®
- Novasen
- Praxis ASA EC 81 Mg Daily Dose

Pharmacologic Category

- Antiplatelet Agent
- Salicylate

Pharmacologic Category Synonyms

- Platelet Aggregation Inhibitor

Use: Labeled Indications

Treatment of mild-to-moderate pain, inflammation, and fever; prevention and treatment of myocardial infarction (MI), acute ischemic stroke, and transient ischemic episodes; management of rheumatoid arthritis, rheumatic fever, osteoarthritis, and gout (high dose); adjunctive therapy in revascularization procedures (coronary artery bypass graft [CABG], percutaneous transluminal coronary angioplasty [PTCA], carotid endarterectomy), stent implantation

Use: Dental

Treatment of postoperative pain

Use: Unlabeled/Investigational

Low doses have been used in the prevention of pre-eclampsia, complications associated with autoimmune disorders such as lupus or antiphospholipid syndrome; alternative therapy for prevention of thromboembolism associated with atrial fibrillation in patients not candidates for warfarin; pericarditis associated with MI; prosthetic valve thromboprophylaxis

Pregnancy Risk Factor

C/D (full-dose aspirin in 3rd trimester - expert analysis)

Pregnancy Considerations

Salicylates have been noted to cross the placenta and enter fetal circulation. Adverse effects reported in the fetus include mortality, intrauterine growth retardation, salicylate intoxication, bleeding abnormalities, and neonatal acidosis. Use of aspirin close to delivery may cause premature closure of the ductus arteriosus. Adverse effects reported in the mother include anemia, hemorrhage, prolonged gestation, and prolonged labor. Aspirin has been used for the prevention of pre-eclampsia; however, the ACOG currently recommends that it not be used in low-risk women. Low-dose aspirin is used to treat complications resulting from antiphospholipid syndrome in pregnancy (either primary or secondary to SLE). In general, low doses during pregnancy needed for the treatment of certain medical conditions have not been shown to cause fetal harm, however, discontinuing therapy prior to delivery is recommended. Use of safer agents for routine management of pain or headache should be considered.

Lactation

Enters breast milk/use caution

Breast-Feeding Considerations

Low amounts of aspirin can be found in breast milk. Milk/plasma ratios ranging from 0.03-0.3 have been reported. Peak levels in breast milk are reported to be at ~9 hours after a dose. Metabolic acidosis was reported in one infant following an aspirin dose of 3.9 g/day in the mother. The AAP states that aspirin should be used with caution while breast-feeding. The WHO considers occasional doses of aspirin to be compatible with breast-feeding, but to avoid long-term therapy and consider monitoring the infant for adverse effects. Other sources suggest avoiding aspirin while breast-feeding due to the theoretical risk of Reye's syndrome.

Contraindications

Hypersensitivity to salicylates, other NSAIDs, or any component of the formulation; asthma; rhinitis; nasal polyps; inherited or acquired bleeding disorders (including factor VII and factor IX deficiency); do not use in children (<16 years of age) for viral infections (chickenpox or flu symptoms), with or without fever, due to a potential association with Reye's syndrome; pregnancy (3rd trimester especially)

Warnings/Precautions

Concerns related to adverse effects:

- Salicylate sensitivity: Patients with sensitivity to tartrazine dyes, nasal polyps, and asthma may have an increased risk of salicylate sensitivity.
- Tinnitus: Discontinue use if tinnitus or impaired hearing occurs.
- Upper gastrointestinal (UGI) events (eg, symptomatic or complicated ulcers): Low-dose aspirin for cardioprotective effects is associated with a two- to fourfold increase in UGI events. The risks of these events increase with increasing aspirin dose; during the chronic phase of aspirin dosing, doses >81 mg are not recommended unless indicated (Bhatt, 2008).

Disease-related concerns:

- Bleeding disorders: Use with caution in patients with platelet and bleeding disorders.
- Dehydration: Use with caution in patients with dehydration.
- Ethanol use: Heavy ethanol use (>3 drinks/day) can increase bleeding risks.
- Gastrointestinal disease: Use with caution in patients with erosive gastritis or peptic ulcer disease.
- Hepatic impairment: Avoid use in severe hepatic failure.
- Renal impairment: Use with caution in patients with mild-to-moderate renal impairment (only at high dosages); avoid in severe impairment.

Concurrent drug therapy issues:

- Alteplase: In the treatment of acute ischemic stroke, avoid aspirin for 24 hours following administration of alteplase; administration within 24 hours increases the risk of hemorrhagic transformation.
- COX-2 inhibitors/NSAIDs: When used concomitantly with 325 mg of aspirin, NSAIDs (including selective COX-2 inhibitors) substantially increase the risk of gastrointestinal complications (eg, ulcer); concomitant gastroprotective therapy (eg, proton pump inhibitors) is recommended (Bhatt, 2008).

Special populations:

- Pediatrics: When used for self-medication (OTC labeling): Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. Changes in behavior (along with nausea and vomiting) may be an early sign of Reye's syndrome; patients should be instructed to contact their healthcare provider if these occur.
- Surgical patients: ASA should be avoided (if possible) in surgical patients for 1-2 weeks prior to surgery, to reduce the risk of excessive bleeding (except in patients with cardiac stents that have not completed their full course of dual antiplatelet therapy [aspirin, clopidogrel]; patient specific situations need to be discussed with cardiologist; AHA/ACC /SCAI/ACS/ADA Science Advisory provides recommendations).

Adverse Reactions

As with all drugs which may affect hemostasis, bleeding is associated with aspirin. Hemorrhage may occur at virtually any site. Risk is dependent on multiple variables including dosage, concurrent use of multiple agents which alter hemostasis, and patient susceptibility. Many adverse effects of aspirin are dose related, and are rare at low dosages. Other serious reactions are idiosyncratic, related to allergy or individual sensitivity. Accurate estimation of frequencies is not possible. The reactions listed below have been reported for aspirin.

Cardiovascular: Dysrhythmias, edema, hypotension, tachycardia

Central nervous system: Agitation, cerebral edema, coma, confusion, dizziness, fatigue, headache, hyperthermia, insomnia, lethargy, nervousness

Dermatologic: Angioedema, rash, urticaria

Endocrine & metabolic: Acidosis, dehydration, hyperglycemia, hypoglycemia (children), hyperkalemia, hypernatremia (buffered forms)

Gastrointestinal: Duodenal ulcers, dyspepsia, epigastric discomfort, gastric erosions, gastric erythema, gastrointestinal ulceration (6% to 31%), heartburn, nausea, stomach pain, vomiting

Hematologic: Anemia, bleeding, coagulopathy, disseminated intravascular coagulation

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(DIC), hemolytic anemia, iron-deficiency anemia, prothrombin times prolonged, thrombocytopenia,

Hepatic: Hepatitis (reversible), hepatotoxicity, transaminases increased

Neuromuscular & skeletal: Rhabdomyolysis, weakness, acetabular bone destruction (OA)

Otic: Hearing loss, tinnitus

Renal: BUN increased, interstitial nephritis, papillary necrosis, proteinuria, renal impairment, renal failure (including cases caused by rhabdomyolysis), serum creatinine increased

Respiratory: Asthma, bronchospasm, dyspnea, hyperpnea, laryngeal edema, noncardiogenic pulmonary edema, respiratory alkalosis, tachypnea

Miscellaneous: Anaphylaxis, low birth weight, peripartum bleeding, prolonged pregnancy and labor, Reye's syndrome, stillbirths

Postmarketing and/or case reports: Cholestatic jaundice, colitis, colonic ulceration, conduction defect and atrial fibrillation (toxicity), coronary artery spasm, delirium, esophageal stricture, esophageal hematoma, esophagitis with esophageal ulcer, ischemic brain infarction, oral mucosal ulcers (aspirin-containing chewing gum), periorbital edema, rectal stenosis (suppository), rhinosinusitis

Metabolism/Transport Effects

Substrate of CYP2C9 (minor)

Drug Interactions

ACE Inhibitors: Salicylates may diminish the antihypertensive effect of ACE Inhibitors. They may also diminish other beneficial pharmacodynamic effects desired for the treatment of CHF. The effects are likely dose-related. 100 mg doses aspirin appear to cause no problems, whereas 300 mg doses appear to significantly affect ACE Inhibitor efficacy. *Risk C: Monitor therapy*

Alendronate: Aspirin may enhance the adverse/toxic effect of Alendronate. Specifically gastrointestinal adverse events. *Risk C: Monitor therapy*

Anticoagulants: Salicylates may enhance the anticoagulant effect of Anticoagulants. *Risk C: Monitor therapy*

Antidepressants (Tricyclic, Tertiary Amine): May enhance the antiplatelet effect of Aspirin. *Risk C: Monitor therapy*

Antiplatelet Agents: May enhance the adverse/toxic effect of Salicylates. Increased risk of bleeding may result. *Risk C: Monitor therapy*

Calcium Channel Blockers (Nondihydropyridine): May enhance the anticoagulant effect of Salicylates. *Risk C: Monitor therapy*

Carbonic Anhydrase Inhibitors: Salicylates may enhance the adverse/toxic effect of Carbonic Anhydrase Inhibitors. Salicylate toxicity might be enhanced by this same combination. *Risk D: Consider therapy modification*

Corticosteroids (Systemic): Salicylates may enhance the adverse/toxic effect of Corticosteroids (Systemic). These specifically include gastrointestinal ulceration and bleeding. Corticosteroids (Systemic) may decrease the serum concentration of Salicylates. Withdrawal of corticosteroids may result in salicylate toxicity. *Risk C: Monitor therapy*

Dasatinib: May enhance the anticoagulant effect of Antiplatelet Agents. *Risk C: Monitor*

therapy

Divalproex: Salicylates may increase the serum concentration of Divalproex. *Risk C: Monitor therapy*

Drotrecogin Alfa: Salicylates may enhance the adverse/toxic effect of Drotrecogin Alfa. Bleeding may occur. *Risk D: Consider therapy modification*

Ginkgo Biloba: May enhance the antiplatelet effect of Salicylates. *Risk D: Consider therapy modification*

Glucosamine: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Heparin: Aspirin may enhance the anticoagulant effect of Heparin. *Risk C: Monitor therapy*

Herbs (Anticoagulant/Antiplatelet Properties) (eg, Alfalfa, Anise, Bilberry): May enhance the adverse/toxic effect of Salicylates. Bleeding may occur. *Risk D: Consider therapy modification*

Ibritumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Ibritumomab. Both agents may contribute to impaired platelet function and an increased risk of bleeding. *Risk C: Monitor therapy*

Ketorolac: May enhance the adverse/toxic effect of Aspirin. *Risk X: Avoid combination*

Ketorolac, Systemic: May enhance the adverse/toxic effect of Aspirin. *Risk X: Avoid combination*

Loop Diuretics: Salicylates may diminish the diuretic effect of Loop Diuretics. Loop Diuretics may increase the serum concentration of Salicylates. *Risk C: Monitor therapy*

Methotrexate: Salicylates may increase the serum concentration of Methotrexate. Salicylate doses used for prophylaxis of cardiovascular events are not likely to be of concern. *Risk D: Consider therapy modification*

Nonsteroidal Anti-Inflammatory Agents: May enhance the adverse/toxic effect of Antiplatelet Agents. An increased risk of bleeding may occur. Nonsteroidal Anti-Inflammatory Agents may diminish the cardioprotective effect of Antiplatelet Agents. This interaction is likely specific to aspirin, and not to other antiplatelet agents. *Risk C: Monitor therapy*

NSAID (Nonselective): May enhance the adverse/toxic effect of Salicylates. An increased risk of bleeding may be associated with use of this combination. NSAID (Nonselective) may diminish the cardioprotective effect of Salicylates. Salicylates may decrease the serum concentration of NSAID (Nonselective). **Exceptions:** Diclofenac. *Risk D: Consider therapy modification*

Omega-3-Acid Ethyl Esters: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Pentosan Polysulfate Sodium: May enhance the adverse/toxic effect of Antiplatelet Agents. Specifically, the risk of bleeding may be increased by concurrent use of these agents. *Risk C: Monitor therapy*

Pentoxifylline: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Pralatrexate: Salicylates may increase the serum concentration of Pralatrexate. Salicylate doses used for prophylaxis of cardiovascular events are unlikely to be of concern. *Risk D:*

Consider therapy modification

Prostacyclin Analogues: May enhance the antiplatelet effect of Antiplatelet Agents. *Risk C: Monitor therapy*

Salicylates: May enhance the anticoagulant effect of other Salicylates. *Risk C: Monitor therapy*

Selective Serotonin Reuptake Inhibitors: May enhance the antiplatelet effect of Aspirin. *Risk C: Monitor therapy*

Serotonin/Norepinephrine Reuptake Inhibitors: May enhance the antiplatelet effect of Aspirin. *Risk C: Monitor therapy*

Sulfonylureas: Salicylates may enhance the hypoglycemic effect of Sulfonylureas. Of concern with regular, higher doses of salicylates, not sporadic, low doses. *Risk C: Monitor therapy*

Thrombolytic Agents: Salicylates may enhance the adverse/toxic effect of Thrombolytic Agents. An increased risk of bleeding may occur. *Risk C: Monitor therapy*

Tiludronate: Aspirin may decrease the serum concentration of Tiludronate. *Risk C: Monitor therapy*

Tositumomab and Iodine I 131 Tositumomab: Antiplatelet Agents may enhance the adverse/toxic effect of Tositumomab and Iodine I 131 Tositumomab. Specifically, the risk of bleeding-related adverse events may be increased. *Risk C: Monitor therapy*

Treprostinil: May enhance the adverse/toxic effect of Salicylates. Bleeding may occur. *Risk C: Monitor therapy*

Uricosuric Agents: Salicylates may diminish the therapeutic effect of Uricosuric Agents. Specifically, uricosuria. *Risk C: Monitor therapy*

Valproic Acid: Salicylates may increase the serum concentration of Valproic Acid. *Risk C: Monitor therapy*

Varicella Virus-Containing Vaccines: Salicylates may enhance the adverse/toxic effect of Varicella Virus-Containing Vaccines. Reye's Syndrome may develop. *Risk D: Consider therapy modification*

Vitamin K Antagonists (eg, warfarin): Salicylates may enhance the anticoagulant effect of Vitamin K Antagonists. *Risk D: Consider therapy modification*

Ethanol/Nutrition/Herb Interactions

Ethanol: Avoid ethanol (may enhance gastric mucosal damage).

Food: Food may decrease the rate but not the extent of oral absorption.

Folic acid: Hyperexcretion of folate; folic acid deficiency may result, leading to macrocytic anemia.

Iron: With chronic aspirin use and at doses of 3-4 g/day, iron-deficiency anemia may result.

Sodium: Hyponatremia resulting from buffered aspirin solutions or sodium salicylate containing high sodium content. Avoid or use with caution in CHF or any condition where hyponatremia would be detrimental.

Benedictine liqueur, prunes, raisins, tea, and gherkins: Potential salicylate accumulation.

Fresh fruits containing vitamin C: Displace drug from binding sites, resulting in increased

urinary excretion of aspirin.

Herb/Nutraceutical: Avoid cat's claw, dong quai, evening primrose, feverfew, garlic, ginger, ginkgo, red clover, horse chestnut, green tea, ginseng (all have additional antiplatelet activity). Limit curry powder, paprika, licorice; may cause salicylate accumulation. These foods contain 6 mg salicylate/100 g. An ordinary American diet contains 10-200 mg/day of salicylate.

Storage

Keep suppositories in refrigerator; do not freeze. Hydrolysis of aspirin occurs upon exposure to water or moist air, resulting in salicylate and acetate, which possess a vinegar-like odor. Do not use if a strong odor is present.

Mechanism of Action

Irreversibly inhibits cyclooxygenase-1 and 2 (COX-1 and 2) enzymes, via acetylation, which results in decreased formation of prostaglandin precursors; irreversibly inhibits formation of prostaglandin derivative, thromboxane A₂, via acetylation of platelet cyclooxygenase, thus inhibiting platelet aggregation; has antipyretic, analgesic, and anti-inflammatory properties

Pharmacodynamics/Kinetics

Duration: 4-6 hours

Absorption: Rapid

Distribution: V_d: 10 L; readily into most body fluids and tissues

Metabolism: Hydrolyzed to salicylate (active) by esterases in GI mucosa, red blood cells, synovial fluid, and blood; metabolism of salicylate occurs primarily by hepatic conjugation; metabolic pathways are saturable

Bioavailability: 50% to 75% reaches systemic circulation

Half-life elimination: Parent drug: 15-20 minutes; Salicylates (dose dependent): 3 hours at lower doses (300-600 mg), 5-6 hours (after 1 g), 10 hours with higher doses

Time to peak, serum: ~1-2 hours

Excretion: Urine (75% as salicylic acid, 10% as salicylic acid)

Dosage

Children:

Analgesic and antipyretic: Oral, rectal: 10-15 mg/kg/dose every 4-6 hours, up to a total of 4 g/day

Anti-inflammatory: Oral: Initial: 60-90 mg/kg/day in divided doses; usual maintenance: 80-100 mg/kg/day divided every 6-8 hours; monitor serum concentrations

Antiplatelet effects: Adequate pediatric studies have not been performed; pediatric dosage is derived from adult studies and clinical experience and is not well established; suggested doses have ranged from 3-5 mg/kg/day to 5-10 mg/kg/day given as a single daily dose. Doses are rounded to a convenient amount (eg, 1/2 of 81 mg tablet).

Mechanical prosthetic heart valves: 6-20 mg/kg/day given as a single daily dose (used in combination with an oral anticoagulant in children who have systemic embolism despite adequate oral anticoagulation therapy (INR 2.5-3.5) and used in combination with low-dose anticoagulation (INR 2-3) and dipyridamole when full-dose oral anticoagulation is contraindicated)

Blalock-Taussig shunts: 1-5 mg/kg/day given as a single daily dose

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Kawasaki disease: Oral: 80-100 mg/kg/day divided every 6 hours; monitor serum concentrations; after fever resolves: 3-5 mg/kg/day once daily; in patients without coronary artery abnormalities, give lower dose for at least 6-8 weeks or until ESR and platelet count are normal; in patients with coronary artery abnormalities, low-dose aspirin should be continued indefinitely

Antirheumatic: Oral: 60-100 mg/kg/day in divided doses every 4 hours

Adults:

Acute ischemic stroke: Oral: 150-325 mg once daily, initiated within 48 hours (in patients who are not candidates for alteplase and not receiving systemic anticoagulation)

Analgesic and antipyretic:

Oral: 325-650 mg every 4-6 hours up to 4 g/day

Rectal: 300-600 mg every 4-6 hours up to 4 g/day

Anti-inflammatory: Oral: Initial: 2.4-3.6 g/day in divided doses; usual maintenance: 3.6-5.4 g/day; monitor serum concentrations

Atrial fibrillation (in patients not candidates for warfarin or at low risk of ischemic stroke): Oral: 75-325 mg once daily

Bioprosthetic aortic valve: Oral: 50-100 mg once daily; usual dose: 81 mg once daily

Bioprosthetic mitral valve (following 3 months of anticoagulation): Oral: 50-100 mg once daily; usual dose: 81 mg once daily

CABG: Oral: 75-100 mg once daily (usual dose: 81 mg) initiated 6 hours following surgery; if bleeding prevents administration at 6 hours after CABG, initiate as soon as possible

CABG (internal mammary bypass graft): Oral: 75-162 mg once daily

Carotid artery stenting: Oral: 81-325 mg once daily beginning at least 24 hours (preferably 4 days) prior to procedure with concomitant clopidogrel

Carotid endarterectomy: Oral: 50-100 mg once daily preoperatively and daily thereafter; usual dose: 81 mg once daily

Infrainguinal arterial reconstruction/bypass: Oral: 75-100 mg once daily (begin preoperatively); usual dose: 81 mg once daily

Mechanical heart valve (with additional risk factors for thromboembolism): Oral: 50-100 mg once daily (in addition to warfarin); usual dose: 81 mg once daily

Mitral annular calcification (with documented stroke, TIA, or systemic embolism): Oral: 50-100 mg once daily; usual dose: 81 mg once daily

Mitral valve prolapse (with documented stroke or TIA): Oral: 50-100 mg once daily; usual dose: 81 mg once daily

Myocardial infarction (primary prevention): Oral: 75-162 mg once daily (Antman, 2004) **or** 75-100 mg (usual dose: 81 mg) once daily (Hirsh, 2008)

Non-ST-segment elevation myocardial infarction (NSTEMI): Oral: Initial: 162-325 mg; Maintenance: 75-100 mg once daily indefinitely; usual maintenance dose: 81 mg once daily

PCI: Oral: Initial: 75-325 mg (300-325 mg in aspirin naive patients) starting at least 2 hours

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(preferably 24 hours) before procedure; post procedure: 162-325 mg once daily (dose and duration varies with type of stent implanted); **Note:** Dose may be reduced to 75-162 mg once daily after appropriate duration based on stent-type is complete

Pericarditis associated with myocardial infarction: Oral: 162-325 mg once daily; doses as high as 650 mg every 4-6 hours may be required

Peripheral arterial disease: Oral: 75-100 mg once daily; usual dose: 81 mg once daily

Pre-eclampsia prevention (unlabeled use): Oral: 60-81 mg once daily (usual dose: 81 mg) during gestational weeks 13-26 (patient selection criteria not established)

Prosthetic valve thromboprophylaxis in pregnancy: Oral: 75-100 mg once daily; usual dose: 81 mg once daily

ST-segment elevation myocardial infarction (STEMI): Oral: Initial: 162-325 mg given on presentation (patient should chew nonenteric-coated aspirin especially if not taking before presentation); for patients unable to take oral, may use rectal suppository (300 mg). Maintenance (secondary prevention): 75-162 mg once daily indefinitely

Stroke (cardioembolic, anticoagulation contraindicated): Oral: 75-325 mg once daily

Stroke/TIA (noncardioembolic, secondary prevention): Oral: 50-325 mg once daily (Adams, 2008) **or** 50-100 mg once daily; usual dose: 81 mg once daily (Hirsh, 2008)

Dosing adjustment in renal impairment: $Cl_{cr} < 10$ mL/minute: Avoid use.

Hemodialysis: Dialyzable (50% to 100%)

Dosing adjustment in hepatic disease: Avoid use in severe liver disease.

Dental Usual Dosing

Postoperative pain:

Analgesic and antipyretic: Oral, rectal:

Children: 10-15 mg/kg/dose every 4-6 hours, up to a total of 4 g/day

Adults: 325-650 mg every 4-6 hours up to 4 g/day

Anti-inflammatory: Oral: Initial:

Children: 60-90 mg/kg/day in divided doses; usual maintenance: 80-100 mg/kg/day divided every 6-8 hours; monitor serum concentrations

Adults: 2.4-3.6 g/day in divided doses; usual maintenance: 3.6-5.4 g/day; monitor serum concentrations

Administration: Oral

Do not crush sustained release or enteric coated tablet. Administer with food or a full glass of water to minimize GI distress. For acute myocardial infarction, have patient chew tablet.

Reference Range

Timing of serum samples: Peak levels usually occur 2 hours after ingestion. Salicylate serum concentrations correlate with the pharmacological actions and adverse effects observed. The serum salicylate concentration (mcg/mL) and the corresponding clinical correlations are as follows: See table.

Serum Salicylate: Clinical Correlations
Serum Salicylate Concentration (mcg/mL) Desired Effects Adverse Effects / Intoxication ~100 Antiplatelet Antipyresis Analgesia GI intolerance

and bleeding, hypersensitivity, hemostatic defects 150-300 Anti-inflammatory Mild salicylism 250-400 Treatment of rheumatic fever Nausea/vomiting, hyperventilation, salicylism, flushing, sweating, thirst, headache, diarrhea, and tachycardia >400-500 Respiratory alkalosis, hemorrhage, excitement, confusion, asterixis, pulmonary edema, convulsions, tetany, metabolic acidosis, fever, coma, cardiovascular collapse, renal and respiratory failure Table has been converted to the following text. **Serum Salicylate: Clinical Correlations Serum salicylate level ~100 mcg/mL:** • Desired effects: Analgesia, antiplatelet, antipyresis • Adverse effects/intoxication: GI intolerance and bleeding, hemostatic defects, hypersensitivity **Serum salicylate level 150-300 mcg/mL:** • Desired effects: Anti-inflammatory • Adverse effects/intoxication: Mild salicylism **Serum salicylate level 250-400 mcg/mL:** • Desired effects: Treatment of rheumatic fever • Adverse effects/intoxication: Diarrhea, flushing, headache, hyperventilation, nausea/vomiting, salicylism, sweating, tachycardia, thirst **Serum salicylate level >400-500 mcg/mL:** • Adverse effects/intoxication: Asterixis, cardiovascular collapse, coma, confusion, convulsions, excitement, fever, hemorrhage, metabolic acidosis, pulmonary edema, renal and respiratory failure, respiratory alkalosis, tetany

Test Interactions

False-negative results for glucose oxidase urinary glucose tests (Clinistix®); false-positives using the cupric sulfate method (Clinitest®); also, interferes with Gerhardt test, VMA determination; 5-HIAA, xylose tolerance test and T₃ and T₄

Dietary Considerations

Take with food or large volume of water or milk to minimize GI upset.

Patient Education

If self-administered, use exactly as directed; do not increase dose or frequency. Adverse reactions can occur with overuse. Take with food or milk. Do not use aspirin with strong vinegar-like odor. Do not crush or chew extended release products. While using this medication, avoid alcohol, excessive amounts of vitamin C, or salicylate-containing foods (eg, curry powder, prunes, raisins, tea, or licorice), other prescription or OTC medications containing aspirin or salicylate, or other NSAIDs without consulting prescriber. Maintain adequate hydration unless instructed to restrict fluid intake. You may experience nausea, vomiting, gastric discomfort (frequent mouth care, small frequent meals, sucking lozenges, or chewing gum may help); GI bleeding, ulceration, or perforation (can occur with or without pain); or discoloration of stool (pink/red). Stop taking aspirin and report ringing in ears; persistent stomach pain; unresolved nausea or vomiting; respiratory difficulty or shortness of breath; unusual bruising or bleeding (mouth, urine, stool); or skin rash. **Pregnancy/breast-feeding precautions:** Inform prescriber if you are or intend to become pregnant. Consult prescriber if breast-feeding.

Geriatric Considerations

Elderly are a high-risk population for adverse effects from nonsteroidal anti-inflammatory agents. As much as 60% of elderly with GI complications to NSAIDs can develop peptic ulceration and/or hemorrhage asymptotically. The concomitant use of H₂ blockers and sucralfate is not effective as prophylaxis with the exception of NSAID-induced duodenal ulcers which may be prevented by the use of ranitidine. Misoprostol and proton pump inhibitors are the only prophylactic agents proven to help prevent the development of NSAID-induced ulcers. Also, concomitant disease and drug use contribute to the risk for GI adverse effects. Use lowest effective dose for shortest period possible. Consider renal function decline with age. Use of NSAIDs can compromise existing renal function especially when Cl_{cr} is <30 mL/minute. Tinnitus may be a difficult and unreliable indication of toxicity due to age-related hearing loss or eighth cranial nerve damage. CNS adverse effects such as confusion, agitation, and hallucination are generally seen in overdose or high dose situations, but elderly may demonstrate these adverse effects at lower doses than younger adults.

Cardiovascular Considerations

Primary Prevention: The U.S. Preventive Services Task Force (USPSTF) recommends the use of aspirin in the following patients:

- Men age 45-79 when the potential benefit due to a reduction in MI risk outweighs the

potential harm due to an increase risk of GI hemorrhage

- Women age 55-79 when the potential benefit due to a reduction in ischemic stroke risk outweighs the potential harm due to an increase risk of GI hemorrhage

The use of aspirin for primary prevention is not recommended for women <55 years of age or men <45 years. In patients >80 years, there is insufficient evidence to recommend routine use of aspirin for primary prevention of cardiovascular disease. Risk assessment for coronary heart disease (CHD) events may be calculated at www.med-decisions.com. Risk assessment for ischemic stroke may be calculated at www.westernstroke.org/PersonalStrokeRisk1.xls. The net benefit is substantial for men at increased risk of MI and women at increased risk of stroke when the risk of GI bleeding is low. Risk factors for GI bleeding with the use of aspirin include increasing age, gender (men>women), upper GI pain, GI ulcers, and concomitant use of NSAIDs. Other risk factors for serious bleeding include uncontrolled hypertension and the concomitant use of anticoagulants. To determine whether the potential benefit of MI prevention (men) and stroke prevention (women) outweighs the potential harm of increased GI hemorrhage, both 10-year cardiovascular (CVD) event risk and age must be considered (see table below). Shared decision making should be encouraged with patients in whom the potential benefits and risks for GI bleeding are closely balanced.

Risk Level at Which CVD Events Prevented (Benefit) Exceeds GI Bleeding Risk (Harm) Men Women Age (in years) 10-year CHD Risk Age (in years) 10-year Stroke Risk 45-59 ?4% 55-59 ?3% 60-69 ?9% 60-69 ?8% 70-79 ?12% 70-79 ?11% **Note:** Table applies to those patients not taking NSAIDs and who do not have upper GI pain or history of GI ulcers. In patients taking NSAIDs or history of GI ulcers, the risk for serious GI bleeding is increased and should be considered when determining the balance of benefit versus harm. Table has been converted to the following text: **Risk Level at Which CVD Events Prevented (Benefit) Exceeds GI Bleeding Risk (Harm)** Men: 45-59 years of age and 10-year CHD risk ?4% 60-69 years of age and 10-year CHD risk ?9% 70-79 years of age and 10-year CHD risk ?12% Women: 55-59 years of age and 10-year stroke risk ?3% 60-69 years of age and 10-year stroke risk ?8% 70-79 years of age and 10-year stroke risk ?11% **Note:** Applies to those patients not taking NSAIDs and who do not have upper GI pain or history of GI ulcers. In patients taking NSAIDs or history of GI ulcers, the risk for serious GI bleeding is increased and should be considered when determining the balance of benefit versus harm.

Secondary Prevention: In unstable angina, aspirin reduces the rate of refractory angina, nonfatal MI, and death. Aspirin reduces the rate of recurrent ischemia and infarction, stroke, and death following MI. In patients who have acute coronary syndrome (ACS) but are not already receiving aspirin, the first dose may be chewed to rapidly establish a high blood level.

Resistance: The definition of biochemical aspirin resistance is measurable, persistent platelet activation that occurs in patients prescribed a therapeutic dose of aspirin. Clinical aspirin resistance is considered aspirin treatment failure; the recurrence of some vascular event despite a regular therapeutic dose of aspirin. Proposed mechanisms of aspirin resistance include poor adherence with therapy, poor absorption, inadequate dosage, drug interactions, increased isoprostane activity, platelet hypersensitivity to agonists, increased COX-2 activity, COX-1 polymorphism, and platelet alloantigen 2 polymorphism of platelet glycoprotein IIIa. Aspirin resistance has been evaluated clinically. A stable group of 326 cardiovascular patients taking 325 mg of aspirin a day for >7 days was prospectively evaluated (Gum PA, 2003). Platelet aggregation was evaluated by optical platelet aggregation using ADP and AA. The primary outcome was defined as a composite of death, MI, or CVA. Seventeen (~5%) patients had biochemical aspirin resistance. Patients who were aspirin-resistant were more likely to have a CV event than those who were aspirin-sensitive (24% vs 10%, CI 1.1-8.9, p = 0.03). There have been other studies evaluating biochemical and clinical aspirin resistance; different methods have been used to determine aspirin resistance. Patient adherence has not been evaluated. Aspirin resistance is likely dose related, may be influenced by dynamic factors yet to be identified and further research is required.

Coronary Artery Stents: The AHA/ACC/SCAI/ACS/ADA Science Advisory (2007) published recommendations (*Circulation*, February 13, 2007) to prevent premature discontinuation of dual antiplatelet therapy (clopidogrel, aspirin) in patients with coronary artery

stents. This advisory panel agreed with the 2004 ACC/AHA guidelines stressing the importance of 12 months of dual antiplatelet therapy after placement of a drug-eluting stent (DES) in patients who are not at high risk of bleeding. The advisory panel included these recommendations. Minor surgery, teeth cleaning, and tooth extraction can usually be performed without increased bleeding on the dual antiplatelet regimen. If increased bleeding is anticipated, then the procedure should be delayed until the antiplatelet regimen is completed. Elective procedures with a significant risk of bleeding should be postponed until the antiplatelet regimen is completed. The Advisory panel recommends healthcare providers who perform invasive or surgical procedures contact the patient's cardiologist before discontinuing antiplatelet therapy. For patients with drug-eluting stents who must undergo a procedure that requires discontinuation of thienopyridine therapy, aspirin should be continued if possible and the thienopyridine restarted as soon as possible after the procedure. "Bridging" stent patients with warfarin, other antithrombins, or glycoprotein IIb/IIIa agents is not supported by the Advisory Committee.

For the complete review and additional recommendations available at: http://www.acc.org/qualityandscience/clinical/pdfs/Final_Dual_Antiplatelet_Statement_010507.pdf. Last accessed January 19, 2007.

Drug Interactions: The question frequently arises as to whether or not concurrent NSAID use interferes with the antiplatelet effects of aspirin. It is known that if taken within 2 hours following an aspirin dose or if taken regularly in a patient on cardioprotective doses of aspirin, ibuprofen will interfere with the antiplatelet effects of aspirin. Less is known about the other NSAIDs, but some data are available. In a pharmacodynamic trial, diclofenac did not interfere with aspirin's antiplatelet effects after six straight days of combined use. In a retrospective analysis, diclofenac did not impact cardiovascular and all-cause mortality when taken regularly in patients receiving daily aspirin. A subgroup analysis of the Physician's Health Study (a primary prevention trial) identified that the use of NSAIDs (specific agents were not identified) at <60 days/year did not diminish aspirin's ability to prevent an initial MI in contrast to taking NSAIDs more frequently. It is surmised that ibuprofen may exhibit greater affinity than aspirin for the COX-1 site or if dosed regularly (or prior to aspirin), it would gain first access to the active site. In either case, aspirin inhibition of COX (irreversible) would be limited in favor of ibuprofen inhibition (reversible).

Dental Health: Effects on Dental Treatment

Key adverse event(s) related to dental treatment: As with all drugs which may affect hemostasis, bleeding is associated with aspirin. Hemorrhage may occur at virtually any site; risk is dependent on multiple variables including dosage, concurrent use of multiple agents which alter hemostasis, and patient susceptibility. Many adverse effects of aspirin are dose related, and are rare at low dosages. Other serious reactions are idiosyncratic, related to allergy or individual sensitivity (see Dental Health Professional Considerations).

Aspirin and clopidogrel (Plavix®) in combination is the primary prevention strategy against stent thrombosis after placement of drug-eluting metal stents in coronary patients. Premature discontinuation of this combination antiplatelet therapy strongly increases the risk of a catastrophic event of stent thrombosis leading to myocardial infarction and/or death, so says a science advisory issued in January 2007 from the American Heart Association in collaboration with the American Dental Association and other professional healthcare organizations. The advisory stresses a 12-month therapy of aspirin and Plavix® combination after placement of a drug-eluting stent in order to prevent thrombosis at the stent site. Any elective surgery should be postponed for 1 year after stent implantation, and if surgery must be performed, consideration should be given to continuing the antiplatelet therapy during the perioperative period in high-risk patients with drug-eluting stents.

This advisory was issued from a science panel made up of representatives from the American Heart Association (AHA), the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, the American College of Surgeons, the American Dental Association (ADA), and the American College of Physicians (Grines, 2007).

Dental Health: Vasoconstrictor/Local Anesthetic Precautions

No information available to require special precautions

Dental Comment

The Food and Drug Administration (FDA), has issued a letter updating information and considerations regarding the use of ibuprofen (400 mg doses) in patients who are taking low dose aspirin (81 mg, immediate release; not enteric coated) for cardioprotection and stroke prevention. Ibuprofen, at these doses, may interfere with aspirin's antiplatelet effect depending upon when it is administered. Patients initiated on aspirin first (for ~1 week) then ibuprofen (400 mg 3 times/day for 10 days) seem to maintain aspirin's platelet effect (Cryer, 2005). Ibuprofen has the greatest impact on aspirin if administered less than 8 hours before aspirin (Catella-Lawson, 2001).

Patients may require counseling about the appropriate timing of ibuprofen dosing in relationship to aspirin therapy. With occasional use of ibuprofen, a clinically-significant interaction with aspirin is unlikely. To avoid interference during chronic dosing, a single dose of ibuprofen should be taken 30-120 minutes after aspirin ingestion or at least 8 hours should elapse after ibuprofen dosing before giving aspirin (FDA, 2006; Catella-Lawson, 2001).

The clinical implications of the interaction are unclear. There have not been any clinical endpoint studies conducted at this time. Avoidance of this interaction is potentially important because aspirin's vascular protection could be decreased or negated.

Other nonselective NSAIDs may have potential for a similar interaction with aspirin. Such has been described with naproxen (Capone, 2005). Acetaminophen does not appear to interfere with the antiplatelet effect of aspirin. Other clinical scenarios (use of smaller ibuprofen doses, other aspirin products, other doses of aspirin) have not been evaluated.

Additional information is available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm125222.htm>

Mental Health: Effects on Mental Status

May cause drowsiness

Mental Health: Effects on Psychiatric Treatment

May cause leukopenia; use caution with clozapine and carbamazepine; may displace valproic acid from binding sites resulting in an increase of unbound drug; monitor for toxicity

Nursing: Physical Assessment/Monitoring

Do not use for persons with allergic reaction to salicylate or other NSAIDs. Assess other medications patient may be taking for additive or adverse interactions. Monitor therapeutic effectiveness and for signs of adverse reactions or overdose at beginning of therapy and periodically with long-term therapy. Assess knowledge/teach patient appropriate use. Teach patient to monitor for adverse reactions, adverse reactions to report, and appropriate interventions to reduce side effects.

Dosage Forms

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. [DSC] = Discontinued product

Caplet:

Bayer® Aspirin Extra Strength: 500 mg

Bayer® Aspirin Regimen Regular Strength: 325 mg

Bayer® Genuine Aspirin: 325 mg

Bayer® Plus Extra Strength: 500 mg [contains calcium carbonate]

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Bayer® with Heart Advantage: 81 mg [contains phytosterols, tartrazine] [DSC]

Bayer® Women's Aspirin Plus Calcium: 81 mg [contains elemental calcium 300 mg] [DSC]

Bayer® Women's Low Dose Aspirin: 81 mg [contains elemental calcium 300 mg]

Caplet, buffered:

Ascriptin® Maximum Strength: 500 mg [contains aluminum hydroxide, calcium carbonate, and magnesium hydroxide]

Gum:

Aspergum®: 227 mg [cherry or orange flavor]

Suppository, rectal: 300 mg, 600 mg

Tablet: 325 mg

Aspercin, Aspirtab: 325 mg

Bayer® Genuine Aspirin: 325 mg

Tablet, buffered: 325 mg

Ascriptin®: 325 mg [contains aluminum hydroxide, calcium carbonate, and magnesium hydroxide]

Buffasal: 325 mg [contains magnesium oxide]

Bufferin®: 325 mg [contains calcium carbonate, magnesium oxide, and magnesium carbonate; contains calcium 65 mg/tablet, magnesium 50 mg/tablet]

Bufferin® Extra Strength: 500 mg [contains calcium carbonate, magnesium oxide, and magnesium carbonate; contains calcium 90 mg/tablet, magnesium 70 mg/tablet]

Buffinol: 325 mg [contains magnesium oxide]

Tablet, chewable: 81 mg

Bayer® Aspirin Regimen Children's: 81 mg [cherry or orange flavor]

St. Joseph® Adult Aspirin: 81 mg [orange flavor]

Tablet, controlled release:

ZORprin®: 800 mg

Tablet, delayed release, enteric coated:

Easprin®: 975 mg

Tablet, enteric coated: 81 mg, 325 mg, 500 mg, 650 mg, 975 mg [DSC]

Bayer® Aspirin Regimen Adult Low Dose, Ecotrin® Low Strength, St. Joseph Adult Aspirin: 81 mg

Ecotrin®, Genacote™: 325 mg

Ecotrin® Maximum Strength: 500 mg

Halfprin®: 81 mg, 162 mg

Pricing: U.S. (www.drugstore.com)

Tablet, controlled release (Zorprin)

800 mg (100): \$125.53

Tablet, EC (Aspirin)

975 mg (90): \$11.25

Tablets (Aspirin)

325 mg (100): \$11.99

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International Brand Names

- AAS (AR, BR, ES)
- Acard (PL)
- Aceprin (MY)
- Acesal (IT)
- Acesan (PL)
- Acetard (FI)
- Aceticil (BR)
- Adiro (MX, VE)
- Albyl-E (NO)
- Alka-Seltzer (AU, PL)
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- Asapor (FI)
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- Aspirin Bayer (HK)
- Aspirin Cardio (SG)
- Aspirin Protect (PL)
- Aspirina (CN, CO, EC)
- Aspirina efervescente (MX)
- Aspirina Junior (MX)
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- Seal and Heal (PL)
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