Fiorinal (aspirin/butalbital/caffeine) - Drug Summary

Actavis Pharma, Inc.

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Fiorinal (aspirin/butalbital/caffeine)

THERAPEUTIC CLASS

Analgesic/barbiturate

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Tension Headache

1-2 caps q4h
Max: 6 caps/day

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: (Butalbital/Aspirin [ASA]/Caffeine) 50mg/325mg/40mg

CONTRAINDICATIONS

Hypersensitivity or intolerance to ASA, caffeine, or butalbital; hemorrhagic diathesis (eg, hemophilia, hypoprothrombinemia, von Willebrand's disease, the thrombocytopenias, thrombasthenia and other ill-defined hereditary platelet dysfunctions, severe vitamin K deficiency and severe liver damage); syndrome of nasal polyps, angioedema, and bronchospastic reactivity to ASA or other NSAIDs; peptic ulcer or other serious GI lesions; porphyria.

WARNINGS/PRECAUTIONS

Not for extended and repeated use. May be habit-forming. Caution in elderly, debilitated, with severe renal/hepatic impairment, hypothyroidism, urethral stricture, head injuries, elevated intracranial pressure, acute abdominal conditions, Addison's disease, prostatic hypertrophy, presence of peptic ulcer, and coagulation disorders. Therapeutic doses of ASA can lead to anaphylactic shock and severe allergic reactions. Significant bleeding possible with peptic ulcers, GI lesions, or bleeding disorders. Caution in children, including teenagers, with chickenpox or flu. Preoperative ASA may prolong bleeding time.

ADVERSE REACTIONS

Drowsiness, lightheadedness, dizziness, N/V, flatulence.

DRUG INTERACTIONS

Caution with anticoagulant therapy; may enhance bleeding. CNS effects enhanced by MAOIs. Additive CNS depression with alcohol, other narcotic analgesics, general anesthetics, tranquilizers (eg, chlordiazepoxide), sedatives/hypnotics, other CNS depressants. May cause hypoglycemia with oral antidiabetic agents and insulin. May cause bone marrow toxicity and blood dyscrasias with 6-mercaptopurine and methotrexate. Increased risk of peptic ulceration and bleeding with NSAIDs. Decreased effects of uricosuric agents (eg, probenecid, sulfinpyrazone). Withdrawal of corticosteroids may cause salicylism with chronic ASA use.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Butalbital: Short- to intermediate-acting barbiturate. ASA: Analgesic, antipyretic, and anti-inflammatory. Caffeine: CNS stimulant. Combines analgesic properties of ASA with anxiolytic and muscle relaxant properties of butalbital.

PHARMACOKINETICS

Absorption: ASA: (650mg dose) T_{max}=40 min, C_{max}=8.8mcg/mL. Butalbital: Well-absorbed; (100mg dose) C_{max}=2020ng/mL, T_{max}=1.5 hrs. Caffeine: Rapid; (80mg dose) C_{max}=1660ng/mL, T_{max}=<1 hr. **Distribution:** ASA: Found in fetal tissue, breast milk; Plasma protein binding (50-80%). Butalbital: Crosses placenta, found in breast milk; Plasma protein binding (45%). Caffeine: Found in fetal tissue, breast milk. **Metabolism:** ASA: Liver; salicyluric acid, phenolic/acyl glucuronides of salicylate, gentisic and gentisuric acid (major metabolites). Caffeine: Liver; 1-methylxanthine and 1-methyluric acid (metabolites). **Elimination:** ASA: Urine; $T_{1/2}$=12 min (ASA), 3 hrs (salicylic acid/total salicylates). Butalbital: Urine (59-88%); $T_{1/2}$=35 hrs. Caffeine: Urine (70%, 3% unchanged); $T_{1/2}$=3 hrs.

ASSESSMENT

Assess for previous hypersensitivity to drug, renal/hepatic function, porphyria, peptic ulcer, other serious GI lesions, bleeding disorders, or any other conditions where treatment is cautioned or contraindicated. Assess for pregnancy/nursing status and possible drug interactions.

MONITORING

Serial monitoring of LFTs and/or renal function with severe hepatic/renal disease. Monitor for anaphylactoid/hypersensitivity reactions, drug abuse/dependence and bleeding.

PATIENT COUNSELING

Advise not to take if patient has ASA allergy. Instruct to take exactly as prescribed; instruct to avoid coadministration with alcohol or other CNS depressants. Advise to avoid hazardous tasks (eg, operating machinery/driving) while on therapy. Counsel that drug may be habit-forming.

STORAGE

Below 25°C (77°F); tight container. Protect from moisture.

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