Fioricet Capsules (acetaminophen/butalbital/caffeine) - Drug Summary

Actavis Pharma, Inc.

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Fioricet
(acetaminophen/butalbital/caffeine)

BOXED WARNING

Associated w/ cases of acute liver failure, at times resulting in liver transplant and death. Most cases of liver injury are associated w/ acetaminophen (APAP) use at doses >4000mg/day, and often involve >1 APAP-containing product.

THERAPEUTIC CLASS

Analgesic/barbiturate

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Tension Headache

1-2 caps q4h prn
Max: 6 caps/day

PEDIATRIC DOSAGE & INDICATIONS

Tension Headache

≥12 Years:
1-2 caps q4h prn
Max: 6 caps/day

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: (Butalbital/APAP/Caffeine) 50mg/300mg/40mg

CONTRAINDICATIONS

Hypersensitivity or intolerance to any component of this product, porphyria.

WARNINGS/PRECAUTIONS

Not for extended and repeated use; may be habit-forming and potentially abusable. Increased risk of acute liver failure in patients w/ underlying liver disease. May cause serious skin reactions (eg, acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis), which can be fatal; d/c at the 1st appearance of skin rash or any other sign of hypersensitivity. Hypersensitivity and anaphylaxis reported; d/c immediately if signs/symptoms occur. Caution w/ severe renal/hepatic impairment, acute abdominal conditions, and in elderly or debilitated patients. Lab test interactions may occur.

ADVERSE REACTIONS

Acute liver failure, drowsiness, lightheadedness, dizziness, sedation, SOB, N/V, abdominal pain, intoxicated feeling.

DRUG INTERACTIONS

CNS effects may be enhanced by MAOIs. May enhance CNS depressant effects of other narcotic analgesics, alcohol, general anesthetics, tranquilizers (eg, chlordiazepoxide), sedative hypnotics, or other CNS depressants. Increased risk of acute liver failure w/ alcohol ingestion.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Butalbital: Short- to intermediate-acting barbiturate. **APAP:** Nonopiate, nonsalicylate analgesic, and antipyretic. **Caffeine:** CNS stimulant. The role each component plays in the relief of the complex of tension headache symptoms is incompletely understood.

PHARMACOKINETICS

Absorption: Butalbital: Well-absorbed. APAP, Caffeine: Rapid. **Distribution:** Found in breast milk. Butalbital: Plasma protein binding (45%); crosses placenta. **Metabolism:** APAP: Liver (glucuronide conjugation). Caffeine: Liver; 1-methylxanthine and 1-methyluric acid (metabolites). **Elimination:** Butalbital: Urine (59-88% unchanged or metabolites); $T_{1/2}$=35 hrs. APAP: Urine (85%); $T_{1/2}$=1.25-3 hrs. Caffeine: Urine (70%, 3% unchanged); $T_{1/2}$=3 hrs.

ASSESSMENT

Assess for hypersensitivity or intolerance to any component of the drug, porphyria, alcohol intake, renal/hepatic impairment, or any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and for possible drug interactions.

MONITORING

Monitor for signs/symptoms of hepatotoxicity, skin/hypersensitivity/anaphylactic reactions, drug abuse/dependence, and other adverse reactions. Monitor effects of therapy w/ serial LFTs and/or renal function tests in patients w/ severe hepatic or renal disease.

PATIENT COUNSELING

Instruct to look for APAP on package labels and not to use >1 APAP-containing product. Instruct to seek medical attention immediately upon ingestion of >4000mg/day of APAP, even if patient is feeling well. Inform that drug may impair mental/physical abilities; advise to avoid performing hazardous tasks (eg, driving/operating machinery). Instruct to avoid drinking alcohol or taking other CNS depressants. Inform that therapy may be habit-forming; advise to take ud. Instruct to d/c and contact physician immediately if signs of allergy (eg, rash or difficulty breathing) develop.

STORAGE

20-25°C (68-77°F).

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