**butalbital, acetaminophen, caffeine†**
(byoo-tal-bit-al, a-seet-a-min-oh-fen, kaf-ee-en)

**Esgic-Plus, Fioricet**

**Classification**

Therapeutic: nonopioid analgesics (combination with barbiturate)

Pharmacologic: barbiturates

**Pregnancy Category C**

† For information on acetaminophen component in formulation, see acetaminophen monograph

**Indications**

Relief of the symptom complex of tension (or muscle contraction) headaches (use should be short-term only as the butalbital component may be habit-forming).

**Action**

Contains an analgesic (acetaminophen) for relief of pain, a barbiturate (butalbital) for its sedative effect, and caffeine, which may be of benefit in tension headaches.

**Therapeutic Effects:** Decreased severity of pain with some sedation.

**Pharmacokinetics**

**Absorption:** Well absorbed.

**Distribution:** Widely distributed; crosses the placenta and enters breast milk.

**Metabolism and Excretion:** Butalbital primarily eliminated by kidneys as unchanged drug or metabolites (59–88% of dose); acetaminophen and caffeine primarily metabolized by liver.

**Half-life:** Butalbital 35 hr; acetaminophen 1–3 hr; caffeine 3 hr.

**TIME/ACTION PROFILE**

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>15–30 min</td>
<td>1–2 hr</td>
<td>6–8 hr</td>
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</table>

**Contraindications/Precautions**

Contraindicated in: Hypersensitivity to individual components; Lactation; Porphyria.

Use Cautiously in:

- History of suicide attempt or drug addiction, Chronic alcohol use, Severe hepatic or renal disease, Severe cardiovascular disease. Patients concomitantly receiving other CNS depressants. Geri: Appears on Beers list. Geriatric patients are at increased risk for side effects (dose reduction recommended); Child: ≤12 yr (safety not established).

**Adverse Reactions/Side Effects**

**CNS:** Drowsiness, confusion, delirium, depression, dizziness, excitement, headache (with alcohol, 71%), insomnia, irritability, kidney, nervousness, numbness, tingling.

**EENT:** Earache, nasal congestion, tinnitus.

**Resp:** Respiratory depression.

**CV:** Palpitations, tachycardia.

**GI:** Constipation, dry mouth, dysphagia, flatulence, distention, anorexia, heartburn.

**Derm:** Dermatitis, pruritus, rash, sweating.

**MS:** Leg pain, muscle weakness.

**Misc:** Urinary, pyrexia, rash, sweating. MI: Jejunal pain, muscle weakness. Misc: Dose: physical dependence, psychological dependence, tolerance.

**Interactions**

**Drug-Drug:** Additive CNS depression with other CNS depressants, including alcohol, anesthetics, antihistamines, antispasmodics, and sedatives/sedatives. May increase the effects of other drugs, including antidiuretics, benzodiazepines, hypoglycians, calcium channel blockers, carbamazepine, clonidine, cyclosporine, cyproheptadine, fluoxetine, fluvoxamine, haloperidol, levodopa, lithium, methylphenidate, metoclopramide, metronidazole, methadone, mifepristone, phenytoin, propranolol, rifampin, risperidone, sertraline, thioridazine, theophylline, venlafaxine, zolpidem, and zuclofenac. May prevent metabolism and increase the effectiveness of butalbital.

**Drug-Natural Products:** St. John's wort, mexican brassica, echinacea, chamomile, hops, or kava kava can increase CNS depression.

**Dosage**

**PO (Adults):** 1–2 capsules or tablets (50–100 mg butalbital) every 4 hr as needed for pain or should not exceed 4 tablets or capsules/4 hr.

**NURSING IMPLICATIONS**

**Assessment**

- Assess type, location, and intensity of pain before and 60 min following administration.

**Nursing Considerations**

- Monitor patient for usefulness and adverse effects.

- **Use cautiously in:** Patients who are elderly, have hepatic or renal impairment, or use of drugs that may cause CNS depression.

- **Contraindications:** Hypersensitivity to any component, porphyria.

- **Precautions:** Pregnancy, lactation, children, infants, elderly, and patients with hepatic or renal impairment.

- **Drug/Lab Interactions:** Increased serum levels of butalbital and/or other CNS depressants.

- **Pharmacologic Class:** Analgesics (NSAIDs), barbiturates.
Prolonged use may lead to physical and psychological dependence and tolerance. This should not prevent patient from receiving adequate analgesia. Most patients who receive butalbital compound for pain do not develop psychological dependence.

Assess frequency of use. Frequent, chronic use can lead to daily headaches in headache-prone individuals because of physical dependence on caffeine and other components. Chronic headaches from overmedication are difficult to treat and may require hospitalization for treatment and prophylaxis.

Potential Nursing Diagnoses

Acute pain (Indications)

Risk for injury (Side Effects)

Implementation

Do not confuse Fiorinal with Fioricet.

Explain therapeutic value of medication before administration to enhance the analgesic effect.

Regularly administered doses may be more effective than prn administration. Analgesic is more effective if given before pain becomes severe.

Medication should be discontinued gradually after long-term use to prevent withdrawal symptoms.

Patient/Family Teaching

Instruct patient to take medication exactly as directed. Do not increase dose because of the habit-forming potential of butalbital. If medication appears less effective over a few weeks, consult health care professional. The dose of acetaminophen should not exceed the maximum recommended daily dose of 4 g/day. Chronic excessive use of 4 g or more can lead to hepatotoxicity, renal or cardiac damage.

Advise patients with tension headaches to take medication at first sign of headache. Lying down in a quiet, dark room may also be helpful. Medications taken for prophylaxis should be continued.

May cause drowsiness or dizziness. Advise patient to avoid driving and other activities requiring alertness until response to medication is known.

Caution patient to avoid concurrent use of alcohol or other CNS depressants.

Advise patient to use an additional nonhormonal method of contraception while taking butalbital compound.

Evaluation/Desired Outcomes

Decrease in severity of pain without a significant alteration in level of consciousness.

Why was this drug prescribed for your patient?