

**Medication Guide**  
**FIORINAL with CODEINE (FYORE-in-ALL)**  
**(Butalbital, Aspirin, Caffeine, and Codeine Phosphate) capsules, CIII**

**FIORINAL with CODEINE is:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is indicated for the relief of the symptom complex of tension (or muscle contraction) headache, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

**Important information about FIORINAL with CODEINE:**

- **Get emergency help right away if you take too much FIORINAL with CODEINE (overdose).** When you first start taking FIORINAL with CODEINE, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking FIORINAL with CODEINE with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your FIORINAL with CODEINE. They could die from taking it. Store FIORINAL with CODEINE away from children and in a safe place to prevent stealing or abuse. Selling or giving away FIORINAL with CODEINE is against the law.

**Important Information Guiding Use in Pediatric Patients:**

- Do not give FIORINAL with CODEINE to a child younger than 12 years of age.
- Do not give FIORINAL with CODEINE to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving FIORINAL with CODEINE to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.

**Do not give FIORINAL with CODEINE to a child or teenager with a viral illness. Reye syndrome, a life-threatening condition, can happen when aspirin (an ingredient in FIORINAL with CODEINE) is used in children and teenagers who have certain viral illnesses.**

**Do not take FIORINAL with CODEINE if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known allergy to nonsteroidal anti-inflammatory drug products (NSAIDs)
- a rare disorder in which your blood doesn't clot normally (hemophilia)

**Before taking FIORINAL with CODEINE, tell your healthcare provider if you have a history of:**

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.
- have been told by your healthcare provider that you are a "rapid metabolizer" of certain medicines

**Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** FIORINAL with CODEINE may harm your unborn baby. Prolonged use of FIORINAL with CODEINE during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended; may harm your baby.
- **taking prescription or over-the-counter medicines, vitamins, or herbal supplements.** Taking FIORINAL with CODEINE with certain other medicines can cause serious side effects that could lead to death.

**When taking FIORINAL with CODEINE:**

- Do not change your dose. Take FIORINAL with CODEINE exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose of 1 or 2 capsules every 4 hours. Total daily dosage should not exceed 6 capsules. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking FIORINAL with CODEINE regularly, do not stop taking FIORINAL with CODEINE without talking to your healthcare provider.
- After you stop taking FIORINAL with CODEINE, dispose the unused FIORINAL with CODEINE in accordance with the local state guidelines and/or regulations.

**While taking FIORINAL with CODEINE DO NOT:**

- Drive or operate heavy machinery, until you know how FIORINAL with CODEINE affects you. FIORINAL with CODEINE can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with FIORINAL with CODEINE may cause you to overdose and die.

**The possible side effects of FIORINAL with CODEINE:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- If you are a nursing mother taking FIORINAL with CODEINE and your breastfeeding baby has increased sleepiness, confusion, difficulty breathing, shallow breathing, limpness, or difficulty breastfeeding.

These are not all the possible side effects of FIORINAL with CODEINE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov)**

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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