

Dual Graphics Inc., Proof Tag

Date: _____

Customer _____

Product Name _____

Folded size: _____

Flat sheet size: _____

of panels: _____

Paper used _____

Colors: _____

Rev.:

Customer Comments/Instructions: _____

Date _____ Our Job # _____

Quantity: _____

- OK as submitted.
- OK with correction(s) indicated. *It is the customer's responsibility to correct spelling, punctuation, and content.*

- Revised proof required:
- Web-based proof (Insite)
 - Plotter proof (Digital Imposition – not for color)
 - High Resolution Inkjet proof
 - PDF Proof (email, FTP link-if over 5 MB)

Authorized Signature

By your signature, you are authorizing us to follow this proof and to continue with production.

D U A L G R A P H I C S

370 Cliffwood Park Street, Brea CA 92821 • Phone 714.990.3700 • Fax 714.990.6818



Medication Guide

Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, C III

Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules are:

- 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules:

- **Get emergency help right away if you take too much Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules (overdose).** When you first start taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules. They could die from taking it. Selling or giving away Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules is against the law.
- Store Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.
- Get emergency help right away if you take more than 4,000 mg of acetaminophen in 1 day. Taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules with other products that contain acetaminophen can lead to serious liver problems and death.

Important Information Guiding Use in Pediatric Patients:

- Do not give Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules to a child younger than 12 years of age.
- Do not give Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules 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 take Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, 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.** Prolonged use of Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules with certain other medicines can cause serious side effects that could lead to death.

When taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules:

- Do not change your dose. Take Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules regularly, do not stop taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules without talking to your healthcare provider.
- After you stop taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, dispose the unused Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules in accordance with the local state guidelines and/or regulations.
- Dispose of expired, unwanted, or unused Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules by taking your drug to an authorized DEA-registered collector or drug take-back program. If one is not available, you can dispose of Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules by mixing the product with dirt, cat litter, or coffee grounds; placing the mixture in a sealed plastic bag, and throwing the bag in your trash.

While taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules DO NOT:

- Drive or operate heavy machinery, until you know how Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules affect you. Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules may cause you to overdose and die.

The possible side effects of Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules:

- 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.
- are a nursing mother taking Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules, 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 Butalbital, Acetaminophen, Caffeine, and Codeine Phosphate Capsules. 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.**

Manufactured by: Nexgen Pharma, Inc., Irvine, CA 92606

Distributed by: Breckenridge Pharmaceutical, Inc., Berlin, CT 06037

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

Revised: 04/2020

6670-0000-99-MG

Rev 04/2020