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 - PDF Proof (email, FTP link-if over 5 MB)

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

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Medication Guide
ASCOMP with Codeine (AZ-komp)
(Butalbital, Aspirin, Caffeine, and Codeine Phosphate, USP) capsules, CIII

ASCOMP 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 ASCOMP with Codeine:

- **Get emergency help right away if you take too much ASCOMP with Codeine (overdose).** When you first start taking ASCOMP 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 ASCOMP 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 ASCOMP with Codeine. They could die from taking it. Selling or giving away ASCOMP with Codeine is against the law.
- Store ASCOMP with Codeine securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Important Information Guiding Use in Pediatric Patients:

- Do not give ASCOMP with Codeine to a child younger than 12 years of age.
- Do not give ASCOMP with Codeine to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving ASCOMP 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 ASCOMP with Codeine to a child or teenager with a viral illness. Reye’s syndrome, a life-threatening condition, can happen when aspirin (an ingredient in ASCOMP with Codeine) is used in children and teenagers who have certain viral illnesses.

Do not take ASCOMP 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 ASCOMP 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.** ASCOMP with Codeine may harm your unborn baby. Prolonged use of ASCOMP 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 ASCOMP with Codeine with certain other medicines can cause serious side effects that could lead to death.

When taking ASCOMP with Codeine:

- Do not change your dose. Take ASCOMP 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 ASCOMP with Codeine regularly, do not stop taking ASCOMP with Codeine without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused ASCOMP with Codeine by taking your drug to an authorized DEA-registered collector or drug take-back program. If one is not available, you can dispose of ASCOMP with Codeine 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 ASCOMP with Codeine DO NOT:

- Drive or operate heavy machinery, until you know how ASCOMP with Codeine affects you. ASCOMP 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 ASCOMP with Codeine may cause you to overdose and die.

The possible side effects of ASCOMP 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 ASCOMP 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 ASCOMP 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.**

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

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