

Quantity Limit

Butalbital Containing Analgesics (brand and generic)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
butalbital and acetaminophen (all brands)	butalbital and acetaminophen	all
butalbital, acetaminophen, and caffeine (all brands)	butalbital, acetaminophen, and caffeine	all
butalbital, acetaminophen, caffeine, and codeine (all brands)	butalbital, acetaminophen, caffeine, and codeine	all
butalbital, aspirin, and caffeine (all brands)	butalbital, aspirin, and caffeine	all
butalbital, aspirin, caffeine, and codeine (all brands)	butalbital, aspirin, caffeine, and codeine	all

Indications

FDA-approved Indications

Butalbital containing products are indicated for the relief of the symptom complex of tension (or muscle contraction) headache.

Evidence supporting the efficacy and safety of these combination products in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because butalbital is habit-forming and potentially abusable.

Butalbital with codeine containing products are indicated for the management of the symptom complex of tension (or muscle contraction) headache when non-opioid analgesic and alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids and butalbital, even at recommended doses, reserve butalbital with codeine containing products for use in patients for whom alternative treatment options (e.g., non-opioid, non-barbiturate analgesics) have not been tolerated or are not expected to be tolerated, or have not provided adequate analgesia or are not expected to provide adequate analgesia.

Initial Limit Quantity

This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

The limit criteria apply to both brand and generic, if available.

Drug	1 Month Limit	3 Month Limit
butalbital 25 mg and acetaminophen 325 mg only	96 units / 25 days	288 units / 75 days
butalbital and acetaminophen	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, and caffeine	48 units / 25 days	144 units / 75 days
butalbital, acetaminophen, caffeine, and codeine	48 units / 25 days	144 units / 75 days
butalbital, aspirin, and caffeine	48 units / 25 days	144 units / 75 days
butalbital, aspirin, caffeine, and codeine	48 units / 25 days	144 units / 75 days

References

1. Allzital [package insert]. Canton, MS: Larken Laboratories, Inc.; June 2022.
2. Ascomp with Codeine [package insert]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; September 2023.
3. Butalbital, Aspirin, and Caffeine [package insert]. Congers, NY: Chartwell RX, LLC; December 2022.
4. Esgic [package insert]. Greenville, NC: Mayne Pharma; May 2019.
5. Fioricet [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; January 2021.
6. Fioricet with Codeine [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
7. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed April 4, 2024.
8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/04/2024).
9. Ailani J, Burch RC, Robbins MS, et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021-1039.