

Reference number(s) 1553-H

Quantity Limit Buprenorphine-Naloxone

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
Suboxone	buprenorphine and naloxone	sublingual tablets and film
Zubsolv	buprenorphine and naloxone	sublingual tablets

Indications

FDA-approved Indications

Buprenorphine and Naloxone Sublingual Tablet (Suboxone Tablet)

Buprenorphine and naloxone sublingual tablets are indicated for the maintenance treatment of opioid dependence. Buprenorphine and naloxone sublingual tablets should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Suboxone Film

Suboxone sublingual film is indicated for treatment of opioid dependence. Suboxone sublingual film should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Zubsolv

Zubsolv is indicated for treatment of opioid dependence. Zubsolv should be used as part of a complete treatment plan that includes counseling and psychosocial support.

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Initial Limit Quantity

This limit is coded for daily dose. Limits do not accumulate together. Patient is allowed the maximum limit for each drug and strength.

Drug	Daily Limit
Suboxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg	3 units / day
Suboxone 12 mg/3 mg	2 units / day
Zubsolv 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg	3 units / day
Zubsolv 8.6 mg/2.1 mg	2 units / day
Zubsolv 11.4 mg/2.9 mg	1 unit / day

References

- 1. Buprenorphine and Naloxone tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; July 2024.
- 2. Suboxone Sublingual Film [package insert]. North Chesterfield, VA: Indivior, Inc.; December 2023.
- 3. Zubsolv [package insert]. Morristown, NJ: Orexo US, Inc.; December 2023.
- 4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 5, 2024.
- 5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/05/2024).
- 6. Cunningham C, Edlund MJ, Fishman M, et al. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 focused update. American Society of Addiction Medicine. January 2020. 1-91.