Reference number(s)
1357-H

Quantity Limit
Methadone
(Oral Concentrate, Dispersible Tablets)

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.

Please note that these methadone products are indicated for detoxification/opioid use disorder ONLY. Methadone products indicated for BOTH detoxification/opioid use disorder AND pain are targeted on the Opioids ER criteria.

Brand Name	Generic Name	Dosage Form
Methadose 10 mg/mL	methadone	oral concentrate
Methadose 40 mg	methadone	dispersible tablets

Indications

FDA-approved Indications

Methadone Concentrate

Methadone hydrochloride oral concentrate contains methadone, an opioid agonist indicated for the:

- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Methadone Dispersible

Methadone hydrochloride tablets for oral suspension contain methadone, an opioid agonist indicated for the:

- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Limitations of Use

Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction

Code of Federal Regulations, Title 42, Sec 8:

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment.

Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment:

- During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction (pursuant to 21 CFR 1306.07(c)), to facilitate the treatment of the primary admitting diagnosis.
- During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility (pursuant to 21 CFR 1306.07(b)).

Initial Limit Quantity

Limits 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 to allow time for refill processing.

The limits for methadone concentrate and dispersible tablets are set to accommodate a 3-day supply.

Drug	1 Month Limit	3 Month Limit
Methadose 10 mg/mL (methadone oral concentrate)	30 mL/25 days	Does Not Apply

Drug	1 Month Limit	3 Month Limit
Methadose 40 mg (methadone dispersible tablet)	9 tablets/25 days	Does Not Apply

References

1. Methadone Concentrate [package insert]. Webster Groves, MO: SpecGx LLC; May 2022.
2. Methadone Dispersible [package insert]. Webster Groves, MO: SpecGX LLC; December 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 30, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/30/2024).
5. U.S. Department of Health & Human Services. Title 21 Code of Federal Regulations: Part 1306.04 Purpose of Issue of Prescription. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1306.04. Accessed October 21, 2024.
6. U.S. Department of Health & Human Services. Substance Abuse and Mental Health Services Administration. Methadone. https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone. Accessed October 21, 2024.