

DOSING GUIDE



Medical Withdrawal for Opioid Dependence

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Suboxone[®]
(buprenorphine HCl/haloxone HCl dihydrate) sublingual tablets

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Dosing Guidance for SUBOXONE & Subutex® (buprenorphine HCl) sublingual tablets

In Short- and Long-term Medical Withdrawal (ie, detoxification)—Inpatient and Outpatient

The goal of medical withdrawal is to rapidly achieve control of withdrawal symptoms so patients can fully participate in treatment, including medical, psychosocial, psychiatric, etc. SUBOXONE and Subutex have been shown to be effective treatments in relieving withdrawal symptoms during medical withdrawal (ie, detoxification) from short-acting opioids and are comparable to, or superior to, other pharmacological treatment options.* Subutex can be administered in a residential setting or physician's office, since it will be administered under supervision. SUBOXONE is the preferred medication for use at home.

The following procedure is recommended:

- Instruct the patient on how to take a sublingual tablet and provide the patient with information about induction.
- To avoid the risk of precipitated withdrawal, the first SUBOXONE or Subutex dose should be administered:
 - When moderate (see Clinical Opiate Withdrawal Scale [COWS] on pages 8 & 9) signs of opioid withdrawal are observed
 - At a dose of 4-8 mg

- Daily dispensing of SUBOXONE or Subutex and review of the patient's status are preferred.
- Doses should be titrated upward according to the patient's:
 - Withdrawal severity
 - Cravings
 - Side effects
 - Other drug use
- Administer the patient's first dose (4 mg of SUBOXONE or Subutex) after moderate opiate withdrawal symptoms have developed. Consider the use of an opioid withdrawal scale for patient assessment (eg, COWS on pages 8 & 9). Remind the patient that opioid withdrawal symptoms are usually alleviated in 20-40 minutes following the first dose of buprenorphine.
- Other withdrawal medications are not routinely required; however, in the event of sleep disturbances, **limited amounts of benzodiazepines (eg, 5-10 mg zolpidem, 10-20 mg temazepam, or 50-100 mg trazodone as sleep aid for 2 nights)** may be prescribed. If benzodiazepines are prescribed, **instruct the patient that severe, potentially lethal, reactions may result from misuse of SUBOXONE or Subutex with benzodiazepines, especially when the two are misused together by injection.**

* Gowing L, Ali R, White J. Buprenorphine for the management of opioid withdrawal (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.

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Outpatient or inpatient dosing regimen

1. Outpatient dosing regimen

- A short-term flexible 5-8 day and a fixed 20-36 day SUBOXONE- or Subutex® (buprenorphine HCl) sublingual tablets—managed medical withdrawal (ie, detoxification) are shown.

Outpatient Dosing Regimen for Opioid Medical Withdrawal

A. FLEXIBLE DOSING SCHEDULE

Day	Recommended upper and lower limits	Recommended buprenorphine dose
1	4 to 8 mg buprenorphine	6 mg buprenorphine
2	4 to 12 mg buprenorphine	8 mg buprenorphine
3	4 to 16 mg buprenorphine	10 mg buprenorphine
4	2 to 12 mg buprenorphine	8 mg buprenorphine
5	0 to 8 mg buprenorphine	4 mg buprenorphine
6	0 to 4 mg buprenorphine	–
7	0 to 2 mg buprenorphine	–
8	0 mg buprenorphine	–

See: National Clinical Guidelines on the Use of Buprenorphine in the Management of Heroin Dependence: Canberra: National Drug Strategy, Commonwealth of Australia. 2001. Lintzeris N, Clark NG, Muhleisen P, et al.

B. FIXED DOSING SCHEDULE

- The same long-term fixed equal dose or percent dose reduction schedule for medical withdrawal can be used in outpatients who have or have not been previously maintained. See Dose Reduction Schedules on page 17 of the Maintenance Therapy section of this booklet.
- If the patient continues using opioids during an outpatient withdrawal episode, helpful options are:
 - Extension of the above regimens over several weeks
 - Transfer of the patient to inpatient withdrawal services (see examples of inpatient reduction schedules)
 - Transfer of the patient to long-term maintenance should be considered

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2. Inpatient dosing regimen

- Inpatient regimens can be adapted according to the degree of monitoring and supervision available.
- Flexible or fixed dosing schedules can be used.
- Flexible and fixed dosing schedules with SUBOXONE or Subutex® (buprenorphine HCl) sublingual tablets are shown below:

Inpatient Dosing Regimen for Opioid Medical Withdrawal

A. FLEXIBLE DOSING SCHEDULE

Day	Recommended buprenorphine dose	Total daily dose
1	4 mg at onset of withdrawal, & additional 2 to 4 mg evening dose pm	4 to 8 mg
2	4 mg morning, with additional 2 to 4 mg evening dose pm	4 to 8 mg
3	4 mg morning, with additional 2 mg evening dose pm	4 to 6 mg
4	2 mg morning pm; 2 mg evening pm	0 to 4 mg
5	2 mg pm	0 to 2 mg
6	no dose	
7	no dose	

See: Buprenorphine dosing regimen for inpatient heroin withdrawal: a symptom-triggered dose titration study. Lintzeris N, Bammer G, Rushworth L, Jolle DJ, Wheliam G. *Drug and Alcohol Dependence*. 2003;70:287-294.

B. FIXED DOSING SCHEDULE

Day	Buprenorphine dose		
	10-day	7-day	3-day
1	8 mg buprenorphine	8 mg buprenorphine	12 mg buprenorphine
2	6 mg buprenorphine	6 mg buprenorphine	8 mg buprenorphine
3	4 mg buprenorphine	4 mg buprenorphine	8 mg buprenorphine
4	4 mg buprenorphine	4 mg buprenorphine	
5	4 mg buprenorphine	2 mg buprenorphine	
6	2 mg buprenorphine	2 mg buprenorphine	
7	2 mg buprenorphine	0 mg buprenorphine	
8	2 mg buprenorphine		
9	2 mg buprenorphine		
10	0 mg buprenorphine		

See: Buprenorphine: how to use it right. Johnson RE, Strain C, Amass L. *Drug and Alcohol Dependence*. 2003;70:S59-S77.

After the withdrawal episode

Having successfully become abstinent, patients should be encouraged to consider further treatment options to help them stay away from opioids. The options should be discussed as early as possible, including the possibility for ongoing psychosocial support and counseling, maintenance therapy, naltrexone treatment, self-help groups, or residential rehabilitation programs. Occasionally patients may, following medical withdrawal, request to be maintained on SUBOXONE (see induction protocol in these guidelines).

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Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's symptoms. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Resting Pulse Rate: _____ beats/minute

Measured after patient is sitting or lying for one minute

0 pulse rate 80 or below

1 pulse rate 81-100

2 pulse rate 101-120

4 pulse rate greater than 120

Sweating: *Over past 1/2 hour not accounted for by room temperature or patient activity*

0 no report of chills or flushing

1 subjective report of chills or flushing

2 flushed or observable moistness on face

3 beads of sweat on brow or face

4 sweat streaming off face

Restlessness: *Observation during assessment*

0 able to sit still

1 reports difficulty sitting still, but is able to do so

3 frequent shifting or extraneous movements of legs/arms

5 unable to sit still for more than a few seconds

Pupil Size:

0 pupils pinned or normal size for room light

1 pupils possibly larger than normal for room light

2 pupils moderately dilated

5 pupils so dilated that only the rim of the iris is visible

Bone or Joint Aches: *If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored*

0 not present

1 mild diffuse discomfort

2 patient reports severe diffuse aching of joints/muscles

4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

GI Upset: *Over last 1/2 hour*

0 no GI symptoms

1 stomach cramps

2 nausea or loose stool

3 vomiting or diarrhea

5 multiple episodes of diarrhea or vomiting

Tremor: *Observation of outstretched hands*

0 no tremor

1 tremor can be felt, but not observed

2 slight tremor observable

4 gross tremor or muscle twitching

Yawning: *Observation during assessment*

0 no yawning

1 yawning once or twice during assessment

2 yawning three or more times during assessment

4 yawning several times/minute

Anxiety or Irritability:

0 none

1 patient reports increasing irritability or anxiousness

2 patient obviously irritable or anxious

4 patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh Skin:

0 skin is smooth

3 piloerection of skin can be felt or hairs standing up on arms

5 prominent piloerection

Runny Nose or Tearing: *Not accounted for by cold symptoms or allergies*

0 not present

1 nasal stuffiness or unusually moist eyes

2 nose running or tearing

4 nose constantly running or tears streaming down cheeks

Total Score _____ (The total score is the sum of all 11 items)

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal.

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