



SUBOXONE® SUBLINGUAL FILM, AUTHORIZED GENERIC OF SUBOXONE® SUBLINGUAL FILM, SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET APPROPRIATE USE CHECKLIST:

This checklist is a useful reminder of the safe use conditions and monitoring requirements for prescribing SUBOXONE (buprenorphine and naloxone) Sublingual Film CIII, Authorized Generic of SUBOXONE (buprenorphine and naloxone) Sublingual Film (CIII), SUBOXONE (buprenorphine and naloxone) sublingual tablets CIII, or SUBUTEX (buprenorphine) sublingual tablets CIII for opioid dependence.

Requirements to address during each patient’s appointment include:

- ▶ understanding and reinforcement of safe use conditions
- ▶ the importance of psychosocial counseling
- ▶ screening and monitoring patients to determine progress towards treatment goals

If a patient continues to abuse various drugs or is unresponsive to treatment, including psychosocial intervention, it is important that you assess the need to refer the patient to a specialist and/or a more intensive behavioral treatment environment.

Additional resource: Physician Clinical Support System: www.pcssmat.org

This checklist may be used during the induction period and filed in patient’s medical record to document safe use conditions. Once a maintenance dose has been established, use the maintenance checklist.

| Measurement to Ensure Appropriate Use | NOTES: |
|--|--------|
| Date: | |
| Induction | |
| <input type="radio"/> Verified patient meets appropriate diagnostic criteria for opioid dependence | |
| <input type="radio"/> Discussed risks described in professional labeling and Medication Guide with patient | |
| <input type="radio"/> Explained or reviewed conditions of safe storage of medication, including keeping it out of the sight and reach of children | |
| <input type="radio"/> Provided induction doses under appropriate supervision | |
| <input type="radio"/> Prescribed limited amount of medication at first visit | |
| <input type="radio"/> Scheduled next visit at interval commensurate with patient stability ▶ Weekly or more frequent visits recommended for the first month | |



SUBOXONE® SUBLINGUAL FILM, AUTHORIZED GENERIC OF SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET APPROPRIATE USE CHECKLIST:

This checklist may be used for visits following the induction period and filed in patient’s medical record to document safe use conditions.

| Measurement to Ensure Appropriate Use | NOTES: |
|--|--------|
| <p>Date:</p> <p>Visit #:</p> | |
| Maintenance | |
| <p><input type="radio"/> Assessed and encouraged patient to take medication as prescribed</p> <p> > Consider pill/film count/dose reconciliation</p> | |
| <p><input type="radio"/> Assessed appropriateness of dosage</p> <p> > Buprenorphine combined with naloxone is recommended for maintenance:</p> <p> —Buprenorphine/Naloxone (SUBOXONE) sublingual film, its Authorized Generic, and (SUBOXONE) sublingual tablets: 16 mg/4 mg is the recommended dose for maintenance</p> <p> —Buprenorphine/Naloxone (Zubsolv®) sublingual tablets: a target dose of 11.4 mg buprenorphine is recommended for maintenance</p> <p> —Buprenorphine/Naloxone (Bunavail®) buccal film: a target dose of 8.4 mg of buprenorphine is recommended for maintenance</p> <p> —Buprenorphine (SUBUTEX) sublingual tablets and generic formulations may be appropriate for maintenance for some patients (e.g., pregnancy, liver disease): 4 mg to 24 mg is the recommended dose range for maintenance</p> <p>Doses higher than this should be an exception</p> <p> > The need for higher dose should be carefully evaluated</p> | |
| <p><input type="radio"/> Conduct urine drug screens as appropriate to assess use of illicit substances</p> | |
| <p><input type="radio"/> Assessed participation in professional counseling and support services</p> | |
| <p><input type="radio"/> Assessed whether benefits of treatment with buprenorphine-containing products outweigh risks associated with buprenorphine-containing products</p> | |
| <p><input type="radio"/> Assessed whether patient is making adequate progress toward treatment goals</p> <p> > Considered results of urine drug screens as part of the evidence of the patient complying with the treatment program</p> <p> > Consider referral to more intensive forms of treatment for patients not making progress</p> | |
| <p><input type="radio"/> Scheduled next visit at interval commensurate with patient stability</p> <p> > Weekly or more frequent visits are recommended for the first month</p> | |

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