Now available

SUBOXONE® *Once-daily dosing*[1]
12 mg and 16 mg tablets

A maintenance dose of SUBOXONE 12-16 mg once daily is clinically effective for most patients*[1]

Effective maintenance dosing with SUBOXONE may help suppress withdrawal and reduce cravings†[1-3]

NEW

Once-daily dosing in a single tablet

Round shape

12 mg 16 mg

SUBOXONE (buprenorphine and naloxone) is indicated for substitution treatment in adults with problematic opioid drug dependence.[1]

N Suboxone®
(buprenorphine and naloxone)

Now available

SUBOXONE® *Once-daily dosing*[1]
12 mg and 16 mg tablets

One tablet, once daily

vs. multiple SUBOXONE tablets may make it more convenient for patients to take their dose‡

Multiple tablets (using 2 mg and 8 mg tablets)	Single tablet (using NEW 12 mg and 16 mg tablets)
	
	

Please consult the product monograph at https://pdf.hres.ca/dpd_pm/00041074.PDF for important information on conditions of clinical use, contraindications, warnings and precautions, adverse reactions, drug interactions, and dosing instructions which have not been discussed in this piece.

The product monograph is also available by calling INDIVIOR Inc. at 1-877-782-6966.

* Doses should not exceed a maximum single daily dose of 24 mg. During maintenance therapy, it may be necessary to periodically re-stabilize the patient to a new maintenance dose in response to changing patient needs.[1]

† In a one-year, multicentre, placebo-controlled study comprising a 4-week, randomized comparison of SUBOXONE, buprenorphine and placebo tablets, there were significantly fewer self-reported cravings in patients treated with 16 mg buprenorphine/naloxone and 16 mg buprenorphine vs. placebo ($p<0.001$).[1]

‡ Comparative clinical significance has not been established.

References: 1. SUBOXONE® Product Monograph. Indivior UK Limited. August 31, 2017. **2**. British Columbia Centre on Substance Use and the Canadian Research Initiative in Substance Misuse. A guideline for the clinical management of opioid use disorder. 2017. Accessed at: http://www.vch.ca/media/Opioid-Addiction-Guideline.pdf. **3**. Fudala PJ, Bridge TP, Herbert S, et al. Office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. *N Engl J Med* 2003;349:949–958.

Suboxone® (buprenorphine and naloxone)

INDIVIOR Focus on you.

P-SBX-CA-00018
EXPIRY January 2020

Suboxone®
(buprenorphine and naloxone)

New to prescribing SUBOXONE®?

SUBOXONE (buprenorphine and naloxone) is indicated for substitution treatment in adults with problematic opioid drug dependence.[1]

Getting your patient started on SUBOXONE®

The timing of the first dose is important to avoid precipitated withdrawal.
Look for objective signs of at least a moderate state of withdrawal.[1]

If your patient is dependent on…

Short-acting opiates

(e.g., heroin and other short-acting opiates)

Dose 1 of SUBOXONE:[1]

- Give when objective signs of opiate withdrawal appear, but
- Not less than 6 hours after the patient last used opiates
- A Clinical Opiate Withdrawal Scale (COWS) score ≥13 may be a useful reference assessment

Long-acting opiates

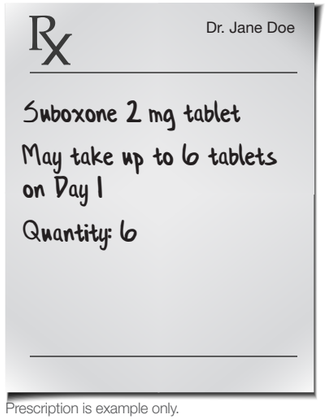
(e.g., extended-release hydromorphone or controlled-release oxycodone when taken as directed)

Dose 1 of SUBOXONE:[1*]

- Give only when objective signs of withdrawal appear
- A COWS score ≥13 may be a useful reference assessment

Baseline liver function tests and documentation of viral hepatitis status are recommended prior to commencing therapy. Regular monitoring of liver function is recommended. Patients who are positive for viral hepatitis, on concomitant medicinal products and/or have existing liver dysfunction are at greater risk of liver injury.[1]

Day 1

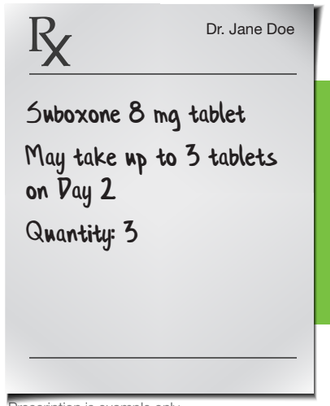


Prescription is example only.

Recommended starting dose: 8 mg[1]

- Initiate with 4 mg
- Additional dose, depending on patient requirement
- Target dose: 8-12 mg

Day 2

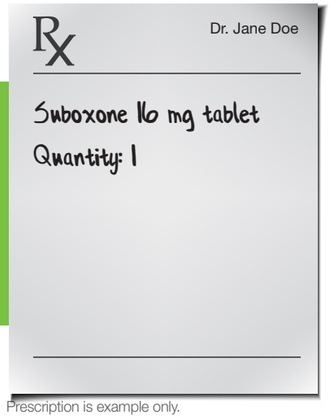


Prescription is example only.

- Titrate in increments or decrements of 2-8 mg to effective maintenance dose (dose should hold patient in treatment and suppress withdrawal effects)†[1]
- Max. dose: 24 mg

Clinical studies have shown that a maintenance dose of 12-16 mg once daily is clinically effective for most patients.[1]

Day 3



Prescription is example only.

- Continue at maintenance dose[1]
- Max. dose: 24 mg

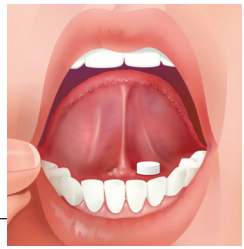
NOTE: **If the patient has relapsed to full agonist opioids…**
Advise patient to suspend resumption of their SUBOXONE until they are in moderate opioid withdrawal, due to the risk of precipitated withdrawal.[1]

After starting a patient on SUBOXONE, they should be rapidly stabilized on an adequate maintenance dose by titrating to clinical effect.[1]

The decision to discontinue SUBOXONE should be made as part of a comprehensive treatment plan.[1]

* For patients currently on methadone, refer to the SUBOXONE product monograph.
† Sample dosage titration. Dosage stabilization and maintenance therapy may not necessarily occur on Day 2 for all patients.

Administration tips



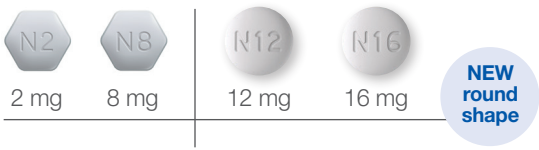
- SUBOXONE® sublingual tablets should be placed under the tongue until dissolved. Dissolution usually occurs within 2 to 10 minutes.[1]
- When multiple tablets are needed to achieve optimal dosage, a patient may place all tablets sublingually at the same time or in two divided portions. The second portion should be placed sublingually directly after the first portion has dissolved.[1]
- Patients should not swallow or consume food or drink until the tablet is completely dissolved.[1]

Missed Dose

Missed doses may contribute to a loss of tolerance to buprenorphine. If your patient has missed their doses of SUBOXONE:

- Ensure they are receiving an appropriate dose on resumption of SUBOXONE treatment.
- The resumption dose may need to be adjusted back to levels used when starting the patient on SUBOXONE.

Now in four dosing strengths



Safety Information

Indications and clinical use:[1]

SUBOXONE® (buprenorphine and naloxone) is indicated for substitution treatment in adults with problematic opioid drug dependence.

The safety and efficacy of SUBOXONE have not been established in adults over 65 years of age. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, respiratory or cardiac function, concomitant disease, or other drug therapy.

Patients prescribed SUBOXONE should be carefully monitored within a framework of medical, social, and psychological support as part of a comprehensive opioid dependence treatment program.

SUBOXONE sublingual tablets should only be prescribed by physicians who meet the following requirements:

i) experience in substitution treatment in opioid drug dependence, and

ii) completion of a recognized SUBOXONE Education Program. For more information about the program, call 1-877-782-6966.

Contraindications:[1]

- Patients who are hypersensitive to buprenorphine, naloxone, or any ingredient in the formulation
- Opioid-naïve patients
- Patients with severe respiratory insufficiency: e.g., acute or severe bronchial asthma, chronic obstructive airway, status asthmaticus, acute respiratory depression and/or cor pulmonale
- Patients with severe hepatic impairment
- Patients with acute alcoholism or delirium tremens and convulsive disorders
- Patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type)
- Patients with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis)
- Patients with severe CNS depression, increased cerebrospinal or intracranial pressure, and head injury
- Patients taking monoamine oxidase inhibitors (or within 14 days of such therapy)

Most serious warnings and precautions:[1]

Limitations of Use: SUBOXONE must be dispensed daily under the supervision of a healthcare professional, until the patient has sufficient clinical stability and is able to safely store SUBOXONE take-home doses. Appropriate security measures should be taken to safeguard stocks of SUBOXONE against diversion.

Addiction, Abuse, and Misuse: Abuse and diversion of buprenorphine have been reported. All patients should be monitored regularly for the development of these behaviours or conditions.

Interaction with Alcohol: The co-ingestion of alcohol with SUBOXONE should be avoided as it may result in dangerous additive effects, causing serious injury or death.

Interaction with other Central Nervous System Depressants: Risks from concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

SUBOXONE sublingual tablets should be placed under the tongue until dissolved. Altering the tablet to take it by routes other than the indicated sublingual route can lead to serious adverse events including death. Do not cut, break, crush or chew SUBOXONE.

Accidental Exposure: Accidental ingestion of even one dose of SUBOXONE by individuals not physically dependent on opioids, especially children, can result in a fatal overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome: Prolonged maternal use of SUBOXONE during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.

Other relevant warnings and precautions:[1]

- Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits
- Risks due to misuse and abuse
- Sub-optimal treatment with SUBOXONE
- Patients dependent on CNS-active substances
- Decreased sex hormone levels and symptoms such as low libido, erectile dysfunction, or infertility
- Life-threatening respiratory depression
- Opioid dependence
- Caution in patients with dysfunction of the biliary tract
- Hepatitis, hepatic events
- Patients with hepatic impairment
- Patients with severe renal impairment
- Allergic reactions
- Miosis and changes in the level of consciousness or changes in the perception of pain as a symptom of disease
- Respiratory depression, hypotension and profound sedation, coma, or death
- Impairment in the ability to drive or operate machinery
- Precipitation of opioid withdrawal symptoms
- Orthostatic hypotension in ambulatory patients
- Caution in patients with a history of circumstances when cerebrospinal pressure may be increased
- May obscure the diagnosis or clinical course in patients with acute abdominal conditions
- Caution in patients with myxedema, hypothyroidism, or adrenal cortical insufficiency (e.g. Addison's disease); toxic psychoses; hypotension, prostatic hypertrophy, or urethral stricture
- Caution in elderly or debilitated patients
- Recommended baseline and regular liver function tests
- Greater risk of liver injury in patients who are positive for viral hepatitis, on concomitant medicinal products and/or have existing liver dysfunction
- Risk of respiratory depression in newborns if buprenorphine is used prior to delivery
- Pregnant and nursing women

For more information:

Please consult the product monograph at https://pdf.hres.ca/dpd_pm/00041074.PDF for more information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The product monograph is also available by calling INDIVIOR Canada Ltd. at 1-877-782-6966.

Reference: 1. SUBOXONE® Product Monograph. Indivior UK Limited. August 31, 2017.

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