ONCE-MONTHLY
Sublocade®
(buprenorphine extended-release) injection for subcutaneous use ©
100mg·300mg

SUBLOCADE® (buprenorphine extended-release) is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

What the new SUBLOCADE storage requirement means for your practice

SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

CONTRAINDICATIONS: SUBLOCADE should not be administered to patients who are hypersensitive to buprenorphine or any component of Indivior's proprietary buprenorphine gel depot delivery system.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Buprenorphine is sought by people with opioid use disorder and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

Risk of Life-Threatening Respiratory Depression and Concomitant Use of Benzodiazepines or Other CNS Depressants with Buprenorphine: Buprenorphine has been associated with life-threatening respiratory depression, overdose, and death, particularly when misused by self-injection or with concomitant use of benzodiazepines or other CNS depressants, including alcohol. Warn patients of the potential danger of self-administration of benzodiazepines, other CNS depressants, opioid analgesics, and alcohol while under treatment with SUBLOCADE. Counsel patients that such medications should not be used concomitantly unless supervised by a healthcare provider.

Use with caution in patients with compromised respiratory function (e.g., chronic obstructive pulmonary disease, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression).

Opioids can cause sleep-related breathing disorders; e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at the time SUBLOCADE is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone. Emphasize the importance of calling 911 or getting emergency help, even if naloxone is administered.

See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING, and Medication Guide.

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What you need to know about SUBLOCADE® transitioning from OA to OAD product supply

The time that SUBLOCADE can be kept at room temperature, once removed from refrigeration, is being updated because of a change in packaging from containing an oxygen absorber (OA) to an oxygen absorbing desiccant (OAD).

What is the difference between the previous OA and new OAD supply storage requirements?

The difference is a significant increase in time for which the new OAD SUBLOCADE supply can be left at room temperature once removed from refrigeration.

Increased from **up to 7 days with previous OA** to **up to 12 weeks with new OAD**

Requirements for previous OA inventory

Store refrigerated at 2°C to 8°C (35.6°F to 46.4°F). Once outside the refrigerator SUBLOCADE may be stored in its original packaging at room temperature, 59°F to 86°F (15°C to 30°C), for up to **7 days prior to administration**.

Requirements for new OAD inventory

Store refrigerated at 2°C to 8°C (35.6°F to 46.4°F). Once outside the refrigerator SUBLOCADE may be stored in its original packaging at room temperature, 59°F to 86°F (15°C to 30°C), for up to **12 weeks prior to administration**.

There may be a transition period in which both previous OA and new OAD product is stored at your practice. Before each use, refer to the full Prescribing Information inside the product packaging, as well as the description on the outside of the product packaging, to ensure proper storage and safe usage.

What does this change mean for my practice?

Increasing SUBLOCADE room temperature storage to up to 12 weeks allows for storage flexibility and possibly less product waste for your practice. Please take measures to prepare your practice by updating your SOPs accordingly.

Can I put the new OAD SUBLOCADE product back in the refrigerator after 12 weeks?

No, discard SUBLOCADE if left at room temperature for longer than 12 weeks.

Should I discard or return the SUBLOCADE product with previous OA packaging?

No, you can safely use it by the expiration date, but continue to adhere to the storage requirements for previous OA product.

Do I need to do anything different with the shipment of new OAD supply?

No, approach immediate storage the same as you did with the previous OA supply [store refrigerated at 2°C to 8°C (35.6°F to 46.4°F)].

Does the new OAD packaging impact efficacy or safety?

No, the efficacy and safety of SUBLOCADE is not different between the previous OA and new OAD packaging.

The enhanced 12-week room temperature storage for SUBLOCADE offers fewer worries about time outside of refrigeration without a change in medication integrity

If you have any additional questions, please reach out to your Indivior representative.

OA=oxygen absorber; OAD=oxygen absorber desiccant; SOP=standard operating procedure.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Risk of Serious Injection Site Reactions: The most common injection site reactions are pain, erythema and pruritus with some involving abscess, ulceration, and necrosis. Some cases resulted in surgical depot removal, debridement, antibiotic administration, and SUBLOCADE discontinuation. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration. Carefully review injection technique.

See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING, and Medication Guide.

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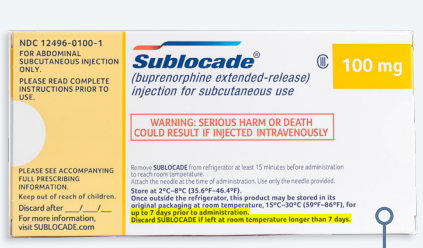
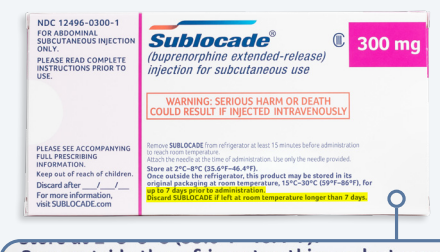
Distinguishing between the OA and OAD SUBLOCADE® supply

Check the packaging for storage requirements

To differentiate the **previous OA** supply from the **new OAD** supply, refer to the storage instructions provided on the packaging. See the highlighted areas below to identify the location of the storage instructions.

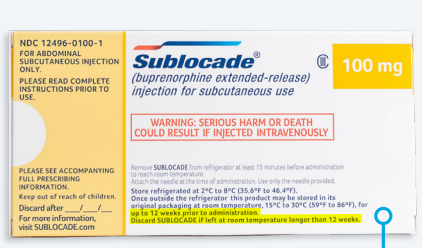
PREVIOUS
OA
packaging

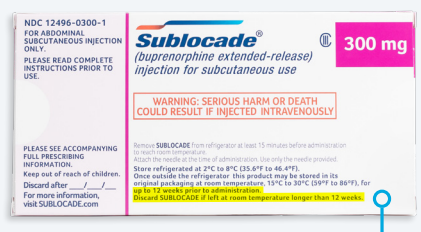




Once outside the refrigerator, this product may be stored in its original packaging at room temperature, 15°C–30°C (59°F–86°F), for **up to 7 days prior to administration.**
Discard SUBLOCADE if left at room temperature longer than 7 days.

NEW
OAD
packaging





Once outside the refrigerator this product may be stored in its original packaging at room temperature, 15°C to 30°C (59°F to 86°F), for **up to 12 weeks prior to administration.**
Discard SUBLOCADE if left at room temperature longer than 12 weeks.

OA=oxygen absorber; OAD=oxygen absorber desiccant.

To learn more about SUBLOCADE, visit SUBLOCADEhcp.com

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. NOWS may be life-threatening if not recognized and treated in the neonate. Newborns should be observed for signs of NOWS and managed accordingly. Advise pregnant women receiving opioid addiction treatment with SUBLOCADE of the risk of neonatal opioid withdrawal syndrome.

Adrenal Insufficiency: Adrenal insufficiency has been reported with opioid use. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off the opioid.

Discontinuation of SUBLOCADE Treatment: Due to the long-acting nature of SUBLOCADE, if treatment is discontinued, monitor patients for several months for withdrawal and treat appropriately.

Inform patients that they may have detectable levels of buprenorphine for a prolonged period of time after treatment with SUBLOCADE. Considerations of drug-drug interactions, buprenorphine effects, and analgesia may continue to be relevant for several months after the last injection.

Risk of Hepatitis, Hepatic Events: Because cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving buprenorphine, monitor liver function tests prior to treatment and monthly during treatment.

Hypersensitivity Reactions: Hypersensitivity to buprenorphine-containing products have been reported most commonly as rashes, hives, and pruritus. Some cases of bronchospasm, angioneurotic edema, and anaphylactic shock have also been reported.

See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING, and Medication Guide.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Precipitation of Opioid Withdrawal in Patients Dependent on Full Agonist Opioids: Buprenorphine may precipitate opioid withdrawal signs and symptoms in persons who are currently physically dependent on full opioid agonists such as heroin, morphine, or methadone before the effects of the full opioid agonist have subsided. Verify that patients have tolerated and are dose adjusted on transmucosal buprenorphine before subcutaneously injecting SUBLOCADE®.

Risks Associated With Treatment of Emergent Acute Pain: When patients need acute pain management, or may require anesthesia, treat patients receiving SUBLOCADE currently or within the last 6 months with a non-opioid analgesic whenever possible. If opioid therapy is required, patients may be treated with a high-affinity full opioid analgesic under the supervision of a physician, with particular attention to respiratory function, as higher doses may be required for analgesic effect and therefore, a higher potential for toxicity exists with opioid administration.

Advise patients of the importance of instructing their family members, in the event of emergency, to inform the treating healthcare provider or emergency room staff that the patient is physically dependent on an opioid and that the patient is being treated with SUBLOCADE.

Use in Opioid Naïve Patients: Because death has been reported for opioid naïve individuals who received buprenorphine sublingual tablet, SUBLOCADE is not appropriate for use in opioid naïve patients.

Use in Patients With Impaired Hepatic Function: Because buprenorphine levels cannot be rapidly decreased, SUBLOCADE is not recommended for patients with pre-existing moderate to severe hepatic impairment. Patients who develop moderate to severe hepatic impairment while being treated with SUBLOCADE should be monitored for several months for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

QTc Prolongation: QT studies with buprenorphine products have demonstrated QT prolongation ≤ 15 msec. Buprenorphine is unlikely to be pro-arrhythmic when used alone in patients without risk factors. The risk of combining buprenorphine with other QT-prolonging agents is not known. Consider these observations when prescribing SUBLOCADE to patients with risk factors such as hypokalemia, bradycardia, recent conversion from atrial fibrillation, congestive heart failure, digitalis therapy, baseline QT prolongation, subclinical long-QT syndrome, or severe hypomagnesemia.

Impairment of Ability to Drive or Operate Machinery: SUBLOCADE may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Caution patients about driving or operating hazardous machinery until they are reasonably certain that SUBLOCADE does not adversely affect their ability to engage in such activities.

Orthostatic Hypotension: Buprenorphine may produce orthostatic hypotension.

Elevation of Cerebrospinal Fluid Pressure: Buprenorphine may elevate cerebrospinal fluid pressure and should be used with caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased. Buprenorphine can produce miosis and changes in the level of consciousness that may interfere with patient evaluation.

Elevation of Intracholedochal Pressure: Buprenorphine has been shown to increase intracholedochal pressure, as do other opioids, and thus should be administered with caution to patients with dysfunction of the biliary tract.

Effects in Acute Abdominal Conditions: Buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Unintentional Pediatric Exposure: Buprenorphine can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it.

ADVERSE REACTIONS: Adverse reactions commonly associated with SUBLOCADE (≥5% of subjects) during clinical trials were constipation, headache, nausea, vomiting, increased hepatic enzymes, fatigue, and injection site pain and pruritus. This is not a complete list of potential adverse events. Please see the full Prescribing Information for a complete list.

DRUG INTERACTIONS

CYP3A4 Inhibitors and Inducers: Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under-dosing.

Serotonergic Drugs: If concomitant use with serotonergic drugs is warranted, monitor for serotonin syndrome, particularly during treatment initiation, and during dose adjustment of the serotonergic drug.

Consult the full Prescribing Information for SUBLOCADE for more information on potentially significant drug interactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor.

Lactation: Buprenorphine passes into the mother's milk. Advise breastfeeding women to monitor the infant for increased drowsiness and breathing difficulties.

Fertility: Chronic use of opioids may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Geriatric Patients: Monitor geriatric patients receiving SUBLOCADE for sedation or respiratory depression.

To report a pregnancy or side effects associated with taking SUBLOCADE or any safety related information, product complaint, request for medical information, or product query, please contact PatientSafetyNA@indivior.com or 1-877-782-6966.

See additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING, and Medication Guide, or for more information about SUBLOCADE, visit www.sublocadehcp.com. For REMS information visit www.sublocadeREMS.com.

Reference: SUBLOCADE [prescribing information]. North Chesterfield, VA: Indivior Inc.

INDIVIOR®

SUBLOCADE is manufactured for Indivior Inc., North Chesterfield VA, 23235.

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Intended for US audiences.

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