

SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous use, CIII, is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who have received an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine at a dose that controls withdrawal symptoms for at least 7 days. SUBLOCADE is part of a complete treatment plan that should include counseling.

KEEP MOVING TOWARDS RECOVERY

with once-monthly ***Sublocade***®



SUBLOCADE continuously releases the medicine buprenorphine all month at sustained levels, with no real daily ups and downs.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SUBLOCADE?

Because of the serious risk of potential harm or death from self-injecting SUBLOCADE into a vein (intravenously), it is only available through a restricted program called the SUBLOCADE REMS Program.

- **SUBLOCADE is not available in retail pharmacies.**
- **Your SUBLOCADE injection will only be given to you by a certified healthcare provider.**

SUBLOCADE contains an opioid medicine called buprenorphine that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.

Important Safety Information continues throughout.

Please see SUBLOCADE [Medication Guide](https://www.sublocade.com) at [sublocade.com](https://www.sublocade.com).

ONCE-MONTHLY

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

SUBLOCADE REDUCED ILLICIT OPIOID USE

With SUBLOCADE, **you've taken an important step** to treat your opioid addiction and to keep moving towards recovery.



In a study, patients who stayed with SUBLOCADE for 6 months were 14x more likely to reach treatment success*

- In a clinical study, 28% of people who took SUBLOCADE plus counseling compared to 2% of patients who took a placebo plus counseling achieved treatment success.

*Treatment success was defined as at least 80% weeks (not always consecutive) free of illicit opioids.



SUBLOCADE blocked the rewarding effects of opioids.†

†In a 12-week study of 39 non-treatment-seeking adults, SUBLOCADE blocked the rewarding effects of opioids.

IMPORTANT SAFETY INFORMATION (CONT'D)

Talk to your healthcare provider about naloxone, a medicine available to patients for emergency treatment of an opioid overdose. If naloxone is given, you must call 911 or get emergency medical help right away to treat overdose or accidental use of an opioid.

Important Safety Information continues throughout.

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TREATMENT IS A LONG-TERM JOURNEY



Limited research suggests less than 3 months of opioid addiction treatment may have minimal benefit. Staying on treatment for a much longer period of time may be associated with more positive long-term results/outcomes.



Opioids hijack your brain and can lead to long-term changes, **so it's important to think about your recovery long term.**



After starting SUBLOCADE, it's important to **stay on your treatment plan and continue your journey.**

IMPORTANT SAFETY INFORMATION (CONT'D)

SUBLOCADE may cause serious and life-threatening breathing problems. Get emergency help if you: feel faint, feel dizzy, are confused, feel sleepy or uncoordinated, have blurred vision, have slurred speech, are breathing slower than normal, or cannot think well or clearly.

Important Safety Information continues throughout.

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PREPARE FOR MOMENTS OF TRANSITION

Staying in recovery can be especially difficult during times of transition. Certain moments in your journey can cause extra stress, which may **increase the risk of relapse**, including:



**BEING RELEASED FROM
INPATIENT TREATMENT
OR “REHAB”**



**RETURNING
HOME**



MOVING



**STARTING A
NEW JOB**

During transition or with increased stress, staying on treatment may help you maintain the progress you’ve made in recovery.



While you can’t control the world around you, you can control your commitment to recovery and to SUBLOCADE.

IMPORTANT SAFETY INFORMATION (CONT’D)

Do not take certain medicines during treatment with SUBLOCADE. Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) while on SUBLOCADE can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBLOCADE.
- You may have detectable levels of SUBLOCADE in your body for a long period after stopping treatment with SUBLOCADE.

Death has been reported in those who are not opioid dependent who received buprenorphine sublingually.

Important Safety Information continues throughout.

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SUPPORT EVERY STEP OF THE WAY

With SUBLOCADE, there may be a path forward. INSUPPORT® offers transition of care support to help you navigate next steps as you continue to move towards recovery.

If you feel you're at risk of relapse or overdose, talk to your healthcare provider.

**Call INSUPPORT at
1-844-467-7778**

IMPORTANT SAFETY INFORMATION (CONT'D)

Who should not take SUBLOCADE?

Do not use SUBLOCADE if you are allergic to buprenorphine or any ingredient in the prefilled syringe (Indivior's proprietary buprenorphine gel depot delivery system, a biodegradable 50:50 poly (DL-lactide-co-glycolide) polymer and a biocompatible solvent, N-methyl-2-pyrrolidone (NMP)).

Before starting SUBLOCADE, tell your healthcare provider about all of your medical conditions, including if you have: trouble breathing or lung problems, a curve in your spine that affects your breathing, Addison's disease, an enlarged prostate gland, problems urinating, liver, kidney, or gallbladder problems, alcoholism, a head injury or brain problem, mental health problems, adrenal gland or thyroid gland problems.

Important Safety Information continues throughout.

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SCHEDULE YOUR NEXT APPOINTMENT TODAY

Making sure you have a provider is important so you can continue treatment. INSUPPORT® can assist patients who receive treatment with SUBLOCADE® with transitioning to a new provider.

FIND A SUBLOCADE PROVIDER NEAR YOU:



www.sublocade.com/find-a-treatment-provider



For additional support, call 1-877-467-7778

IMPORTANT SAFETY INFORMATION (CONT'D)

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor. If you receive SUBLOCADE while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated.
- **breastfeeding or plan to breastfeed.** SUBLOCADE can pass into your breast milk and harm your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with SUBLOCADE. Monitor your baby for increased drowsiness and breathing problems.

Important Safety Information continues throughout.

Please see SUBLOCADE [Medication Guide](#) at sublocade.com.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

What should I avoid while being treated with SUBLOCADE?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBLOCADE affects you.** Buprenorphine can cause drowsiness and slow reaction times. SUBLOCADE can make you sleepy, dizzy, or lightheaded. This may happen more often in the first few days after your injection and when your dose is changed.
- **You should not drink alcohol** or take prescription or over-the-counter medicines that contain alcohol during treatment with SUBLOCADE, because this can lead to loss of consciousness or even death.

What are the possible side effects of SUBLOCADE?

SUBLOCADE can cause serious side effects, including:

- **Trouble breathing.** Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants during treatment with SUBLOCADE can cause breathing problems that can lead to coma and death.
- **Sleepiness, dizziness, and problems with coordination.**
- **Physical dependence.**
- **Liver problems.** Call your healthcare provider right away if you notice any of these symptoms: your skin or the white part of your eyes turns yellow (jaundice), dark or “tea-colored” urine, light colored stools (bowel movements), loss of appetite, pain, aching, or tenderness on the right side of your stomach area, or nausea.
- Your healthcare provider should do blood tests to check your liver before you start and during treatment with SUBLOCADE.
- **Allergic reaction.** You may have a rash, hives, swelling of your face, wheezing low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.

Important Safety Information continues throughout.

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IMPORTANT SAFETY INFORMATION (CONT'D)

- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms: shaking, sweating more than normal, feeling hot or cold more than normal, runny nose, watery eyes, goose bumps, diarrhea, vomiting, or muscle aches.
- **Decrease in blood pressure.** You may feel dizzy when you get up from sitting or lying down.
- **The most common side effects of SUBLOCADE include:** constipation, headache, nausea, injection site itching, vomiting, increase in liver enzymes, tiredness, or injection site pain.
- SUBLOCADE may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects. Call your healthcare provider for medical advice about side effects.

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. You are encouraged to report negative side effects of drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about SUBLOCADE, see the [full Prescribing Information including BOXED WARNING](#), and [Medication Guide](#), visit www.sublocade.com or talk to your healthcare provider. For REMS information visit www.sublocadeREMS.com.

SUBLOCADE is manufactured by
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