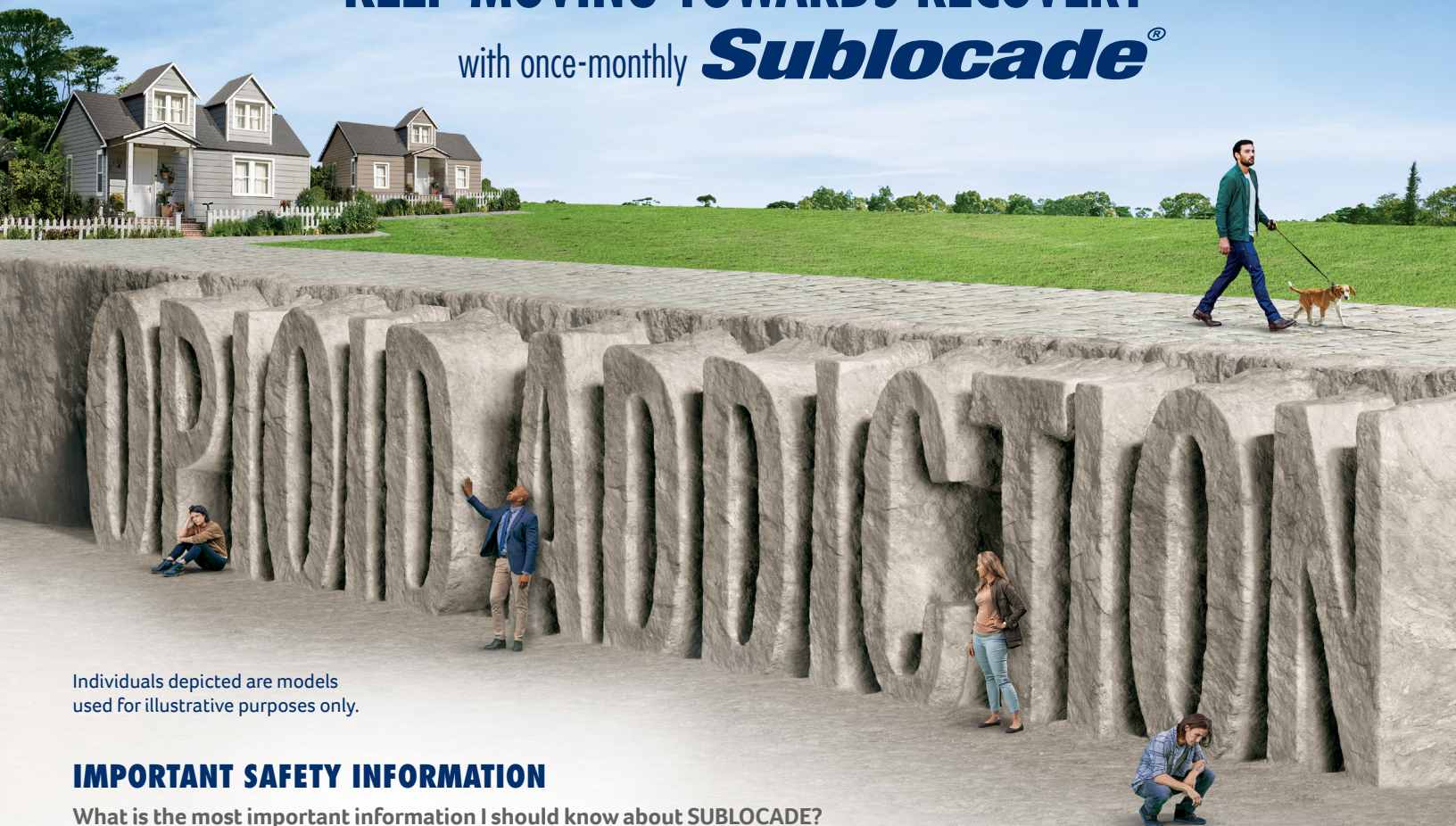


SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous use, CIII, is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who have received an oral transmucosal (used under the tongue or inside the cheek) 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***®



Individuals depicted are models
used for illustrative purposes only.

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.

Important Safety Information continues throughout.

Please see the 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



Opioid addiction may be an overwhelming problem. But don't give up.

Living with opioid addiction can be a struggle. But it's important to understand that even when someone tries again and again to quit, it's not a sign of weakness or failure.

Opioid addiction is actually a disease called Opioid Use Disorder (OUD), and it involves compulsive drug seeking and use, despite negative consequences. That's because opioids hijack the brain and physically change it. This can make it really hard for someone to stop using opioids on their own, but there's help.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the 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.

SUBLOCADE may cause serious and life-threatening breathing problems. Get emergency help right away 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.

There are different ways to tackle it.

Medication-assisted treatment (MAT), which combines medication and counseling, is an option that can help manage opioid addiction long term.

According to the US Department of Health and Human Services, for some people MAT is the most effective approach to treat OUD.

If you've decided to seek treatment for opioid addiction, you've already made a move towards recovery.

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.

Important Safety Information continues throughout.

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

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Why it’s so hard to quit

When we do something we enjoy, like eat a delicious meal or have a good time with family and friends, a chemical called dopamine is released in our brain and we feel pleasure. This is how our brains are wired to learn what makes us feel good, which drives us to keep repeating these natural rewards.

Dopamine is also released when someone takes opioids—**opioids trigger a surge of dopamine**, causing an increased sense of pleasure compared to natural rewards. This powerfully motivates someone to use opioids. At this point, the naturally rewarding things that were enjoyable can’t compete with the effect of opioids.

Trapped in the cycle of opioid addiction

Use

Taking opioids and feeling “high” or relief from negative moods or feelings.

Withdrawal

Experiencing uncomfortable or negative physical and emotional symptoms after stopping opioids. May not feel normal when opioids are not taken.

Craving

An intense desire to take opioids again to experience pleasure. This can become all-consuming and uncontrollable.



IMPORTANT SAFETY INFORMATION (CONT’D)

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

The physical effects opioid addiction has on the brain can also change behavior. **Medication-assisted treatment (MAT)** combines medication and counseling to treat both the physical and behavioral parts of opioid addiction to help people reach and maintain recovery.

Medication

Different medications can be used in MAT, and buprenorphine is an effective option.

Buprenorphine helps the brain get used to functioning without illicit opioids. At prescribed doses, buprenorphine was designed to have a weaker effect on the brain compared to illicit opioids and not cause a “high.” These doses can then reduce cravings, while blocking other opioids from causing rewarding effects, which can make taking them less appealing.

Counseling

Counseling can help people deal with the emotions and behaviors that are often linked to addiction. It can also teach long-term skills that can help people better manage stressful situations and start positive routines.

MAT has been shown to be more effective than medication or counseling alone.

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)).

Important Safety Information continues throughout.

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



WHY MAT IS PROVEN EFFECTIVE

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ONCE-MONTHLY SUBLOCADE

can help you keep moving towards recovery

SUBLOCADE is the first once-monthly extended-release form of buprenorphine. Buprenorphine is a type of medicine used in medication-assisted treatment (MAT).

In a clinical study, SUBLOCADE patients were 14x more likely to achieve treatment success*

28% of people with SUBLOCADE plus counseling compared to 2% of people with placebo plus counseling.

*In a 24-week study, treatment success was defined as opioid-free at least 80% of the weeks in treatment. Opioid-free means urine sample tested negative for illicit opioids plus no self-reported use of opioids. Weeks were not always consecutive.

Continuously releases the medicine buprenorphine all month

No real daily ups and downs.

Blocks the rewarding effects of opioids.† Rewarding effects are the feelings that can keep people using.

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

Individual results may vary.

Provides sustained levels of buprenorphine throughout the month



IMPORTANT SAFETY INFORMATION (CONT'D)

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 (men), problems urinating, liver, kidney, or gallbladder problems, alcoholism, a head injury or brain problem, mental health problems, adrenal gland or thyroid gland problems.

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** 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. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

IMPORTANT SAFETY INFORMATION (CONT'D)

- **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 if you breastfeed during treatment with SUBLOCADE.

Important Safety Information continues throughout.

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

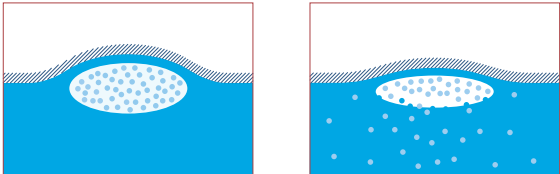
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CONTINUOUS DELIVERY

SUBLOCADE is a medicine that’s injected by a healthcare professional as a liquid, and once inside the body, turns to a solid gel called a depot (dee-poh).

The depot gradually releases medicine at a controlled rate all month



IMAGES ARE FOR ILLUSTRATIVE PURPOSES ONLY.

Learn about the administration process on page 13.

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?

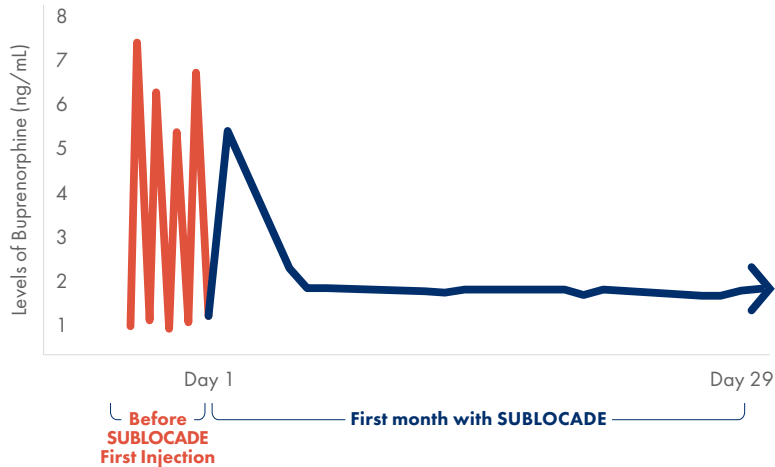
- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBLOCADE affects you.** SUBLOCADE can make you sleepy, dizzy, or lightheaded. This may happen more often in the first few days after your injection and when your dose is changed.

SUSTAINED LEVELS ALL MONTH



Daily Buprenorphine

Monthly SUBLOCADE



IMPORTANT SAFETY INFORMATION (CONT'D)

- **Do 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.

Important Safety Information continues throughout.

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

How SUBLOCADE was studied*

- In a clinical study, levels of buprenorphine in participants’ blood were measured. Participants were first given daily oral transmucosal buprenorphine to control withdrawal symptoms and once stabilized, switched to treatment with once-monthly SUBLOCADE
- After SUBLOCADE administration, buprenorphine levels peaked at 24 hours, then decreased to approximate target levels that were maintained throughout the month
- The graph represents average buprenorphine blood levels observed, and individual results may vary

*Data were gathered during a 12-week study of 39 participants designed to measure if SUBLOCADE 300 mg blocked the rewarding effects of an opioid (hydromorphone 6 mg or 18 mg). Blood samples were not collected daily, and the graph on the left represents average buprenorphine blood levels observed. Before starting treatment with SUBLOCADE, patients must be stabilized for at least 7 days on oral transmucosal buprenorphine (8-24 mg/day).

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A TREATMENT PLAN WITH COUNSELING

Counseling is an important part of recovery and treatment with SUBLOCADE.

There are counseling options that can work with your schedule and budget. There’s one-on-one therapy, group therapy, even online, phone, and text therapy.

For resources and help finding opioid addiction treatment centers in your area, talk to your healthcare provider and visit:

- The Substance Abuse and Mental Health Services Administration (SAMHSA) at findtreatment.gov

IMPORTANT SAFETY INFORMATION (CONT’D)

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.**

Other ways to keep moving towards recovery

Sticking to your treatment plan and continuing counseling are critical. Because recovery will always come with challenges, here are some other things you can do to stay on track:

- **Make appointment reminders.** Going for check-ups and monthly treatment will help you manage your symptoms. Try adding reminders on your phone.
- **Keep up with counseling.** Think of your counselor as a “coach.” They’re there to help you find ways to stay on track when things get tough.
- **Keep a daily diary.** Jot down how you feel emotionally and physically. Whether you’re feeling okay or having symptoms such as cravings or withdrawal, tell your healthcare provider and counselor. This can help them understand how your treatment is going.

Any journey towards recovery will be challenging. Remember, you can do this. Keep going!



IMPORTANT SAFETY INFORMATION (CONT’D)

- **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.

Important Safety Information continues throughout.

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

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STARTING TREATMENT

Once you and your treatment provider decide SUBLOCADE is right for you, treatment can start.

Induction period

Before you receive SUBLOCADE, you'll need to first take a daily transmucosal form of buprenorphine (under the tongue or inside the cheek) for at least 7 days to help control withdrawal symptoms and help you transition to SUBLOCADE.

Make sure your follow-up appointment is scheduled.

People who have Opioid Use Disorder have an elevated risk for opioid overdose. Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for emergency treatment of an opioid overdose. It is not a treatment for Opioid Use Disorder.

IMPORTANT SAFETY INFORMATION (CONT'D)

- **Allergic reaction.** You may have a rash, hives, itching, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.

When you go to your appointment to receive SUBLOCADE, here's what to expect:

SUBLOCADE is an injection that's administered by your treatment provider. It's given just under the skin (subcutaneously) in your abdomen.

After it's injected as a liquid, SUBLOCADE turns into a solid called a depot (dee-poh) that gradually releases medication throughout the month. The depot may be seen or felt as a small bump under the skin at the injection site on your abdomen. Over time, as medication is released into your body, the bump will get smaller. Everyone's experience is different. Ask your treatment provider if you have questions about the depot size.

Do not try to remove the depot, and do not rub or massage the injection site. Likewise, try not to let belts or waistbands rub against the injection site.



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.

Important Safety Information continues throughout.

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

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injection for subcutaneous use **100mg • 300mg**

WHAT TO KNOW ABOUT DOSING

You'll receive SUBLOCADE once a month (at least 26 days between doses). **If you miss a dose, please see your treatment provider as soon as possible.**

- SUBLOCADE comes in 2 doses: 300 mg and 100 mg.
- Your treatment provider will start with 300 mg to help the medication reach an effective level in your body.
 - After 2 months at 300 mg monthly, the recommended maintenance dose is 100 mg monthly. Some patients may later need a dose increase to 300 mg monthly.

The level of medicine in your blood is important. Ask your treatment provider about how the delivery system used in SUBLOCADE maintains monthly medicine levels even when the dose is lowered (e.g., from 300 mg to 100 mg on month 3).

IMPORTANT SAFETY INFORMATION (CONT'D)

- **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.

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.

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Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the 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.

SUBLOCADE may cause serious and life-threatening breathing problems. Get emergency help right away 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 (CONT'D)

- 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.

Important Safety Information continues throughout.

Please see the SUBLOCADE Medication Guide at sublocade.com.



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.

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You may pay as little as \$0 per monthly dose of SUBLOCADE, if eligible

If you're prescribed SUBLOCADE for on-label use and have private insurance, you may qualify for copay assistance offered through the INSUPPORT® Copay Assistance Program. If you qualify, you may pay as little as \$0 per monthly dose of SUBLOCADE, which can help with out-of-pocket costs. Program is applicable to medical expenses of the drug, not administration costs. The offer may be applied for a maximum of 14 doses per calendar year; certain service date restrictions apply.

The Copay Assistance Program is valid ONLY for patients with private insurance who are prescribed SUBLOCADE for on-label use. Patients with government insurance are not eligible for the Copay Assistance Program, including, but not limited to, Medicare, Medicaid, Medigap, VA, DOD, TriCare, CHAMPVA, or any other federally or state-funded government-assisted program. Other restrictions apply.

For more information, please refer to the [Terms and Conditions](#) for the INSUPPORT® Copay Assistance Program for SUBLOCADE.

For most people with public or private insurance, SUBLOCADE is covered. Check with your insurance provider for more details.

If you don't have insurance, INSUPPORT® may help you learn about other potential coverage sources you may qualify for with Alternative Funding Information.

Learn about savings and coverage assistance at [INSUPPORT.com/specialty-product/patient/resources](https://www.insupport.com/specialty-product/patient/resources)

IMPORTANT SAFETY INFORMATION (CONT'D)

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LEARN ABOUT STARTING TREATMENT

See what to expect when you start SUBLOCADE
[Watch the video at SUBLOCADE.com/resources](https://www.sublocade.com/resources)

IMPORTANT SAFETY INFORMATION (CONT'D)

See [full Prescribing Information](#), including [BOXED WARNING](#), and [Medication Guide](#), or for more information about SUBLOCADE, visit www.sublocade.com. For REMS information visit www.sublocadeREMS.com.

Important Safety Information continues throughout.

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

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(buprenorphine extended-release)
injection for subcutaneous use
100mg-300mg

INDICATION

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.

IMPORTANT SAFETY INFORMATION

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

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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.

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 (men), problems urinating, liver, kidney, or gallbladder problems, alcoholism, a head injury or brain problem, mental health problems, adrenal gland or thyroid gland problems.

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** 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. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **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 if you breastfeed during treatment with SUBLOCADE.

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.** 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.
- **Do 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, itching, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.
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- **The most common side effects of SUBLOCADE include:** constipation, headache, nausea, injection site itching, vomiting, increase in liver enzymes, tiredness, or injection site pain.
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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.

See full Prescribing Information, including **BOXED WARNING**, and **Medication Guide**, or for more information about SUBLOCADE, visit www.sublocade.com. For REMS information visit www.sublocadeREMS.com.

TALK TO A HEALTHCARE PROVIDER ABOUT ***Sublocade®***

Keep moving towards recovery with once-monthly SUBLOCADE

- In a clinical study, SUBLOCADE patients were 14x more likely to achieve treatment success*: 28% of people with SUBLOCADE plus counseling compared to 2% of people with placebo plus counseling

*In a 24-week study, treatment success was defined as opioid-free at least 80% of the weeks in treatment. Opioid-free means urine sample tested negative for illicit opioids plus no self-reported use of opioids. Weeks were not always consecutive.

- Continuously releases the medicine buprenorphine all month with no real daily ups and downs

- Blocks the rewarding effects of opioids,[†] which are the feelings that can keep people using

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

- Is part of a complete treatment plan with counseling
- For most people with public or private insurance, SUBLOCADE is covered. Check with your insurance provider for more details

IMPORTANT SAFETY INFORMATION

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