

MEDICATION GUIDE

SUBLOCADE (SUB-lo-kade) (buprenorphine extended-release) injection, for subcutaneous use, (CIII)

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 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 people 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 medical 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
 - cannot think well or clearly
- **Do not take SUBLOCADE with certain medicines. Taking SUBLOCADE with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) 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 several months after stopping treatment with SUBLOCADE.

What is SUBLOCADE?

SUBLOCADE is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who:

- have started treatment with a single dose of a buprenorphine medicine in the form of a sublingual tablet or buccal film (transmucosal) or
- are already being treated with buprenorphine.

SUBLOCADE is part of a complete treatment plan that should include counseling and psychosocial support.

Who should not receive SUBLOCADE?

Do not receive SUBLOCADE if you are allergic to buprenorphine or any ingredients in the prefilled syringe (ATRIGEL® delivery system). See the end of this Medication Guide for a list of ingredients in SUBLOCADE.

Before receiving SUBLOCADE, tell your healthcare provider about all 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 to 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. Talk with your healthcare provider before starting any new medicines during or after stopping treatment with SUBLOCADE.

How will I receive SUBLOCADE?

- You will receive SUBLOCADE by your healthcare provider as an injection just under the skin (subcutaneous) of your stomach (abdomen), thigh, buttock, or back of the upper arm. After the first two injections, you will receive SUBLOCADE monthly (with at least 26 days between doses).

- If you are not currently receiving buprenorphine treatment, your healthcare provider will give you a test dose of buprenorphine first to see if you are able to tolerate it, before switching to SUBLOCADE.
- SUBLOCADE is injected as a liquid. After the injection, SUBLOCADE changes to a solid form called a depot. The depot may be seen or felt as a small bump under your skin at the injection site for several weeks. The depot will get smaller over time.
- Do not try to remove the depot.
- Do not rub or massage the injection site.
- Try not to let any restrictive clothing such as belts, waistbands, or sleeves rub against the injection site.
- If you miss a dose of SUBLOCADE, see your healthcare provider to get your SUBLOCADE injection as soon as possible.

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 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 SUBLOCADE with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants can cause breathing problems that can lead to coma and death.
- **Sleepiness, dizziness, and problems with coordination.**
- **Physical dependence or abuse.**
- **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
 - 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, light-headedness, feeling faint or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **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
 - 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
- 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 of SUBLOCADE.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

General information about SUBLOCADE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

What are the ingredients in SUBLOCADE?

Active ingredient: buprenorphine

ATRIGEL® Delivery system: biodegradable 50:50 poly(DL-lactide-co-glycolide) polymer and a biocompatible solvent, *N*-methyl-2-pyrrolidone (NMP).

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For more information, go to www.SUBLOCADE.com or call 1-877-782-6966.

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