

## **SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous use, CIII**

### **IMPORTANT SAFETY INFORMATION**

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

- Because of 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 which 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, which is a medicine that is available to patients for emergency treatment of an opioid overdose. If naloxone is given, 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, dizzy, confused, sleepy or uncoordinated, have blurred vision or slurred speech, are breathing slower than normal or 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.

#### **Who should not receive SUBLOCADE?**

**Do not receive SUBLOCADE** if you are allergic to buprenorphine or any ingredient in the prefilled syringe (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, problems urinating, liver, kidney, gallbladder or mental health problems, alcoholism, head injury or brain problem, adrenal or thyroid gland problems.

**Tell your healthcare provider if you are pregnant or breastfeeding or plan to become pregnant or breastfeed:**

- 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.
- 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 before starting any new medicines and during or after stopping treatment with SUBLOCADE.

**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, especially 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 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, 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 rash, hives, itching, 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, 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 contact [PatientSafetyNA@indivior.com](mailto: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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

See [full Prescribing Information, including BOXED WARNING](#), and [Medication Guide](#). For REMS information visit [www.sublocadeREMS.com](http://www.sublocadeREMS.com).