# AN IMPORTANT ALERT TO KEEP WITH YOU

In case of a medical emergency, healthcare providers may ask for your medical history to help choose the appropriate medication for you. This Patient Alert Card will let healthcare providers know that you are being treated with SUBLOCADE® (buprenorphine extended-release).

COMPLETE THE CARD, REMOVE IT FROM THIS PAGE, FOLD IT IN HALF, AND KEEP IT ON YOUR PERSON AT ALL TIMES. THIS CARD CAN FIT IN A WALLET, PURSE, OR BACKPACK.

# **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?

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.

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.

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
- · cannot think well or clearly

PATIENT ALERT CARD  In the event that you require medical attention, show this card to a healthcare provider.  My Name	
My Primary Care Provider	Number – –
My Treatment Provider	Number
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PATIENT ALERT CARD	

# IMPORTANT SAFETY INFORMATION CONTINUES ON REVERSE

Please see the attached Medication Guide or visit www.sublocade.com.

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# **IMPORTANT SAFETY INFORMATION (CONT.)**

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

#### **PATIENT ALERT CARD**

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- Your SUBLOCADE injection will only be given to you by a certified healthcare provider.

See reverse and see the full Prescribing Information including BOXED WARNING, and Medication Guide at www.sublocade.com

SUBLOCADE® (buprenorphine extended-release)

exists with opioid administration.

 Closely monitor patients who require opioid therapy for analgesis, with particular attention to respiratory function. Higher doses of opioids may be needed for analgesic effect. Therefore, a higher potential for toxicity

• If a situation arises in which this patient needs acute pain management, treat with a non-opioid analgesic whenever possible.

This patient is being treated with SUBLOCADE (buprenorphine extended-release). CIII, 100mg/300mg, a once-monthly subcutaneous injection.

# PATIENT ALERT CARD

#### 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.

**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.

# IMPORTANT SAFETY INFORMATION CONTINUES ON NEXT PAGE

Please see the attached Medication Guide or visit www.sublocade.com.

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# **IMPORTANT SAFETY INFORMATION (CONT.)**

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
  - 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.
- 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. Call your healthcare provider for medical advice about side effects.

To report pregnancy or side effects associated with taking SUBLOCADE, please call 1-877-782-6966. You are encouraged to report negative side effects of drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

For more information about SUBLOCADE, the full <u>Prescribing Information including BOXED WARNING</u>, and <u>Medication Guide</u>, visit <u>www.sublocade.com</u> or talk to your healthcare provider.

For REMS information visit www.sublocadeREMS.com.

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