

## **Important Safety Information about Sublocade**

### **What is Sublocade®?**

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. It is a once monthly injection placed below the skin that gradually releases in the body over time.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

### **Warnings & Precautions**

**Addiction, Abuse, and Misuse:** SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

**Respiratory Depression:** Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

**Neonatal Opioid Withdrawal Syndrome:** Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

**Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

**Risk of Opioid Withdrawal With Abrupt Discontinuation:** If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

**Risk of Hepatitis, Hepatic Events:** Monitor liver function tests prior to and during treatment.

**Risk of Withdrawal in Patients Dependent on Full Agonist Opioids:** Verify that the patient is clinically stable on transmucosal buprenorphine before injecting SUBLOCADE.

**Treatment of Emergent Acute Pain:** Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

## **Adverse Reactions**

Adverse reactions commonly associated with SUBLOCADE (in  $\geq 5\%$  of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.