9/2021

רוקח/ת יקר/ה, רופא/ה יקר/ה,

הנדון: עדכון עלון לתכשיר
SUBLOCADE 100 mg (163-66-35771-00)
SUBLOCADE 300 mg (163-67-35780-00)
Extended-release solution for injection for abdominal subcutaneous use

הרכב החומר הפעיל:

SUBLOCADE 100 mg:
Buprenorphine 100 mg/0.5 ml

SUBLOCADE 300 mg:
Buprenorphine 300 mg/1.5 ml

התוויה מאושרת:

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients over 15 years of age who have been induced and clinically stabilized on a transmucosal buprenorphine-containing product.
SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

השינויים המודגשים ברקע צהוב מהווים החמרה כתוספת למידע הקיים. בהודעה זו נכללות תוספות ההחמרות בלבד. קיימים שינויים נוספים שאינם מהווים החמרה ואינם נכללים בהודעה זו.

7 **WARNINGS AND PRECAUTIONS**

7.3 Risk of Life-Threatening Respiratory and Central Nervous System (CNS) Depression

Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of getting emergency medical help right away in the event of a known or suspected overdose.

Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose

Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver.

Because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose, strongly consider prescribing naloxone for the emergency treatment of opioid overdose, both when initiating and renewing treatment with SUBLOCADE. Also consider prescribing naloxone if the patient has household members (including children) or other close contacts at risk for accidental ingestion or opioid overdose.

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Advise patients and caregivers that naloxone may also be administered for a known or suspected overdose with buprenorphine itself. Higher than normal doses and repeated administration of naloxone may be necessary due to the long duration of action of buprenorphine and its affinity for the mu-opioid receptor *[see Overdosage (12)]*.

Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone. Emphasize the importance of getting emergency medical help, even if naloxone is administered.

7.4 Managing Risks From Concomitant Use of Benzodiazepines Or Other CNS Depressants With Buprenorphine

If concomitant use is warranted, strongly consider prescribing naloxone for the emergency treatment of opioid overdose, as is recommended for all patients in buprenorphine treatment for opioid use disorder *[see Warnings and Precautions (7.3)]*.

7.5 Risk of Serious Injection Site Reactions

Injection site reactions are most commonly manifested by pain, erythema and pruritis. In some post-marketing case reports injection site reactions have involved abscess, ulceration, and necrosis. Some cases resulted in surgical depot removal, debridement, antibiotic administration, and SUBLOCADE discontinuation. The likelihood of serious injection site reactions may be increased with inadvertent intramuscular or intradermal administration. Carefully review injection technique *[see Instructions for Use (5.5)]*. Evaluate and treat serious injection site reactions as appropriate.

9 DRUG INTERACTIONS

Table 4. Clinically Significant Drug Interactions

Benzodiazepines and Other Central Nervous System (CNS) Depressants

Intervention: If concomitant use is warranted, strongly consider prescribing naloxone for the emergency treatment of opioid overdose, as is recommended for all patients in treatment for opioid use disorder *[see Warnings and Precautions (7.3)]*.

Muscle Relaxants

Intervention: Due to the risk of respiratory depression with concomitant use of skeletal muscle relaxants and opioids, strongly consider prescribing naloxone for the emergency treatment of opioid overdose *[see Warnings and Precautions (7.3, 7.4)]*.

העלון לרופא של התכשיר נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות של משרד הבריאות. ניתן לקבלו מודפס על ידי פנייה לבעל הרישום.

בברכה,

מג'ר נעמי שאקו עזרא
רוקחת ממונה

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