3/2022

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.

14.2 Pharmacodynamics

……

Pharmacodynamic Interaction with Fentanyl

An open-label, cross-over study was conducted in 8 opioid-tolerant subjects to assess the ability of intravenous buprenorphine to prevent respiratory depression associated with high doses of fentanyl administered in a clinical setting. Opioid-tolerant subjects were medically stable and taking oral morphine equivalents of ≥ 90 mg daily with no other CNS depressant use. Buprenorphine infusions at three dose levels and placebo infusions were administered, followed by up to four doses of fentanyl. The three intravenous buprenorphine dose levels were designated as low (0.25 mg/70kg bolus + 0.1 mg/70kg/hr), mid (0.5 mg/70kg bolus + 0.2 mg/70kg/hr), and high (1.25 mg/70kg bolus + 0.5 mg/70kg/hr). The low, mid, and high buprenorphine dose levels produced average plasma concentrations (from 2 hours to 6 hours after infusion onset) of 1.06 ng/mL, 2.26 ng/mL, and 6.04 ng/mL, respectively.

Escalating intravenous fentanyl boluses of 0.25, 0.35, 0.50 and 0.70 mg/70 kg (up to a maximum single cumulative dose of 1.8 mg/70 kg) were administered over 90 seconds at +2hr, +3hr, +4hr and +5hr after the start of intravenous infusion of buprenorphine or placebo to assess a potential impact of apnea events after each fentanyl bolus are shown in Figure 11. Four of the 8 subjects in the placebo infusion groups discontinued prior to the fourth fentanyl bolus because of apnea (2 after the second bolus and 2 after the third bolus); 3 of the remaining 4 subjects experienced apnea after the fourth fentanyl dose. All 8 subjects in the buprenorphine infusion groups completed the fentanyl boluses and 2 of the 8 experienced apnea.

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

נעמי שאקו עזרא-שרותי רוקחות
16 Hagaon Eliyahu St. Ramat Gan 52364
Tel: 972 54 4610844, Fax: 972 3 6774471
naomi@nsereg.com www.nsereg.com
רח' הגאון אליהו 16 רמת גן 52364
טל': 054-4610844 פקס: 03-6774471