אפריל 2023

רופא/ה, רוקח/ת נכבד/ה,

הנדון: BuTrans Transdermal Patches -עדכון עלון לרופא
***(BuTrans 5* -135-70-31151-00, *BuTrans 10*-135-71-31152-00, *BuTrans 15*- 157-99-34931-00, *BuTrans 20*-135-72-31153-00)**

מעבדות רפא בע"מ מבקשת להודיעך על עדכון בעלון לרופא של התכשירים שבנדון.

מרכיב פעיל: Buprenorphine
חוזקים: BuTrans 5mcg/h, BuTrans 10mcg/h, BuTrans 15mcg/h, BuTrans 20mcg/h

התוויה:
Treatment of moderate to severe opioid responsive chronic pain conditions which are not adequately responding to non-opioid analgesics.

פרטי העדכון העיקריים הינם:
(טקסט שהושמט מסומן באדום עם קו חוצה, טקסט שנוסף מסומן בכחול, טקסט המהווה החמרה מודגש בצהוב)

4.4 Special warnings and precautions for use

BuTrans should be used with particular caution in patients with severely impaired respiratory function, sleep apnoea, acute alcohol intoxication, head injury, shock, a reduced level of consciousness of uncertain origin, intracranial lesions or increased intracranial pressure, severe hepatic impairment (see section 4.2) or constipation.

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4.5. Interaction with other medicinal products and other forms of interaction

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Pharmacodynamic interactions:

BuTrans should be used cautiously with:

~~o~~Other central nervous system depressants: ~~such as~~ other opioid derivatives (analgesics and antitussives containing e.g., morphine, dextropropoxyphene, codeine, ~~or~~ dextromethorphan or noscapine).~~,~~ ~~c~~Certain antidepressants, sedative H1- receptor antagonists, alcohol, anxiolytics, neuroleptics, clonidine and related substances. These combinations increase the CNS depressant activity.

~~The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation,~~ Benzodiazepines: This combination can potentiate respiratory depression~~, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited~~ of central origin (see section 4.4 and BOX Warning).

At typical analgesic doses buprenorphine is a partial mu-receptor agonist but it is described to function as a pure mu receptor agonist. In ***BuTrans*** clinical studies subjects receiving full mu agonist opioids (up to 90 mg oral morphine or oral morphine equivalents per day) were transferred to

BuTrans. There were no reports of abstinence syndrome or opioid withdrawal during conversion from entry opioid to ***BuTrans*** (see section 4.4).

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4.8. Undesirable effects

General disorders and administration site conditions
Very common (≥1/10) - Application site skin ~~site~~ reactions*

5.2. Pharmacokinetic properties

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Each patch provides a steady delivery of buprenorphine for up to seven days. Steady state is achieved during the first application. After removal of ***BuTrans,*** buprenorphine concentrations initially decline~~,~~ at a rate of ~~decreasing~~ approximately 50% in 12 hours ~~(range 10–24 h)~~. Thereafter, mean elimination half-lives have been reported to be between 30 and 45 hours.

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למידע המלא יש לעיין בעלון בשלמותו.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות (www.health.gov.il), וניתן לקבל העתק מודפס שלו באמצעות פנייה לבעל הרישום, מעבדות רפא בע"מ, בטל' 02-5893939 או בכתובת דוא"ל RA@rafa.co.il.

בכבוד רב,

נטלי קפלן

רוקחת ממונה