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XXXX

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

Tramadol Medochemie 100mg/2ml

חברת דיפריס ושות' בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.

ההתוויה הרשומה של התכשיר בישראל: Moderate to severe pain

צורת המתן של התכשיר : solution for injection/infusion

מרכיב פעיל: Tramadol hydrochloride 50mg/1ml

בהודעה זו מצוינים סעיפים בהם נעשה עדכון המהווה החמרה - מודגש **בצהוב**.
בעלון נעשו עדכונים נוספים שאינם מהווים החמרה ואינם מצויינים כאן.

עדכונים בעלון נעשו בסעיפים הבאים:

4.4 Special warnings and precautions for use

Sleep-related breathing disorders

Opioids can cause sleep-related breathing disorders including central sleep apnea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.

Drug dependence, tolerance and potential for abuse

For all patients, prolonged use of this product may lead to drug dependence (addiction), **even at therapeutic doses**. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression). Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.

A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.

Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance.

The risks of developing tolerance should be explained to the patient.

Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.

Patients should be closely monitored for signs of misuse, abuse, or addiction. The clinical need for analgesic treatment should be reviewed regularly.

Drug withdrawal syndrome

The opioid drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

Hyperalgesia

Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain.

This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose.

1.1 Fertility, pregnancy and lactation

Pregnancy

Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.

If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.

Breast-feeding

Administration to nursing women is not recommended as tramadol may be secreted in breast milk and may cause respiratory depression in the infant.

4.8 Undesirable effects

Psychiatric disorders:

Frequency unknown: drug dependence (see section 4.4)

Metabolism and nutrition disorders:

Uncommon: drug withdrawal syndrome.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#!/byDrug>

ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת חברת דיפריס ושות' בע"מ, רחוב הברזל 32,
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בברכה,
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