



02.2021

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

### Tramal Injection 100

חברת טק-או-פארם ליברה בע"מ מבקשת להודיע כי העלון לרופא עודכן.  
מכתב זה כולל החמרות בלבד המסומנות בצהוב. ישנם שינויים נוספים בתוכן העלון  
שאינם מצוינים במכתב זה.  
הרכב התכשיר- מרכיב פעיל:

Tramadol Hydrochloride 100mg/2ml

התוויה מאושרת:

Moderate to severe pain

צורת המינון:

Solution for Injection

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י  
פנייה לבעל הרישום: חברת טק-או-פארם ליברה בע"מ, ת.ד. 45054, ירושלים.

בכבוד רב,

חברת טק-או-פארם ליברה בע"מ

### ההחמרות בעלון לרופא 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.

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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.

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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.

Tramadol is not suitable as a substitute in opioid-dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms

#### 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..

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#### 4.6 Fertility, pregnancy and lactation

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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.

Tramadol - administered before or during birth - does not affect uterine contractility.

Administration during labour may depress respiration in the neonate and an antidote for the

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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.

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### **4.8 Undesirable effects**

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Symptoms of drug withdrawal syndrome, similar to those occurring during opiate withdrawal, may occur as follows: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol discontinuation include: panic attacks, severe anxiety, hallucinations, paraesthesias, tinnitus and unusual CNS symptoms (i.e. confusion, delusions, depersonalisation, derealisation, paranoia).

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