



10.2021

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  
העלונים שאינם מצוינים במכתב זה.  
הרכב התכשירים- מרכיב פעיל:

Tramadol Hydrochloride 100 MG / 2 ML

התוויה מאושרת:

Moderate to severe pain

צורת המתן:

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

##### Serotonin syndrome

Serotonin syndrome, a potentially life-threatening condition, has been reported in patients receiving tramadol in combination with other serotonergic agents or tramadol alone (see sections 4.5, 4.8 and 4.9).

If concomitant treatment with other serotonergic agents is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose escalations.

Symptoms of serotonin syndrome may include mental status change, autonomic instability, neuromuscular abnormalities and/or gastrointestinal symptoms.

Serotonin syndrome is likely when one of the following is observed:

Spontaneous clonus

Inducible or ocular clonus with agitation or diaphoresis

Tremor and hyperreflexia

Hypertonia and body temperature  $> 38^{\circ}\text{C}$  and inducible or ocular clonus

If serotonin syndrome is suspected, a dose reduction or discontinuation of therapy should be considered depending on the severity of the symptoms. Withdrawal of the serotonergic drugs usually brings about a rapid improvement.

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

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Concomitant therapeutic use of tramadol and serotonergic drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors (see section 4.3), tricyclic antidepressants and mirtazapine may cause serotonin syndrome, a potentially life-threatening condition (see sections 4.4 and 4.8) toxicity. Serotonin syndrome is likely when one of the following is observed:

- Spontaneous clonus
- Inducible or ocular clonus with agitation or diaphoresis
- Tremor and hyperreflexia
- Hypertonia and body temperature  $> 38^{\circ}\text{C}$  and inducible ocular clonus.

Withdrawal of the serotonergic drugs usually brings about a rapid improvement. Treatment depends on the type and severity of the symptoms.

#### 4.8 Undesirable effects

*Nervous system disorders:*

*Very common:* dizziness

*Common:* headache, somnolence

*Rare:* paraesthesia, tremor, epileptiform convulsions, involuntary muscle contractions, abnormal coordination, syncope, speech disorders.

Not known: Serotonin syndrome

#### 4.9 Overdose

*Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.*

##### *Symptoms*

In principle, on intoxication with tramadol symptoms similar to those of other centrally acting analgesics (opioids) are to be expected. These include in particular miosis, vomiting, cardiovascular collapse, consciousness disorders up to coma, convulsions and respiratory depression up to respiratory arrest.

Serotonin syndrome has also been reported.