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פברואר 2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

Tramadol Medochemie 100mg/2ml

שלום רב,

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

העדכון בעלון כולל הוספה של מידע מהותי חדש, מידע בטיחותי חדש וכן שינויי ניסוח.

בהודעה זו מצוינים סעיפים בעלון בהם עודכן מידע מהותי חדש או מידע בטיחותי חדש (החמרה המסומנת בצהוב):

4. Clinical particulars

WARNING: RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death [see section 4.4 'Special warnings and precautions for use']. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Limit dosages and durations to the minimum required.

Follow patients for signs and symptoms of respiratory depression and sedation.

4.2 Posology and method of administration

Treatment goals and discontinuation

Before initiating treatment with Tramadol Medochemie 100 mg/2 ml Solution for Injection, a treatment strategy including treatment duration and treatment goals, and a plan for end of the treatment, should be agreed together with the patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust

dosages if needed. When a patient no longer requires therapy with tramadol, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered (see section 4.4).

4.4 Special warnings and precautions for use

Tolerance and opioid use disorder (abuse and dependence)

Tolerance, physical and psychological dependence, and opioid use disorder (OUD) may develop upon repeated administration of opioids such as Tramadol Medochemie 100 mg/2 ml Solution for Injection. Repeated use of Tramadol Medochemie 100 mg/2 ml Solution for Injection can lead to opioid use disorder (OUD). A higher dose and longer duration of opioid treatment can increase the risk of developing OUD. Abuse or intentional misuse of Tramadol Medochemie 100 mg/2 ml Solution for Injection may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).

Patients will require monitoring for signs of drug-seeking behaviour (e.g. too early requests for refills). This includes the review of concomitant opioids and psycho-active drugs (like benzodiazepines). For patients with signs and symptoms of OUD, consultation with an addiction specialist should be considered.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת חברת דיפריס ושות' בע"מ, רחוב הברזל 32, תל-אביב, טל. 03-6444950

בברכה,

מירי חזן
רוקחת ממונה