

אוקטובר 2025

רופא/ה, רוקח/ת נכבד/ה,

## Methadone – עדכון עלון

מעבדות רפא מבקשת להודיעך על עדכון בעלון לצרכן בפורמט עלון של התכשירים שבנדון.

מרכיב פעיל: Methadone HCl  
 חוזק: 50 mg/ml  
 התוויה:

Methadone is indicated for the:  
 Relief of severe pain.  
 Detoxification and withdrawal treatment in narcotic addiction.

### פרטי העדכון העיקריים הינם:

(טקסט שהושמט מסומן באדום עם קו חוצה, טקסט שנוסף מסומן בכחול, טקסט המהווה החמרה מודגש בצהוב).

### עלון לצרכן בפורמט עלון לרופא:

## 5 WARNINGS AND PRECAUTIONS

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### 5.8 Opioid-Induced Hyperalgesia and Allodynia

Opioid-Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. This condition differs from tolerance, which is the need for increasing doses of opioids to maintain a defined effect [see Dependence (9.2)]. Symptoms of OIH include (but may not be limited to) increased levels of pain upon opioid dosage increase, decreased levels of pain upon opioid dosage decrease, or pain from ordinarily non-painful stimuli (allodynia). These symptoms may suggest OIH only if there is no evidence of underlying disease progression, opioid tolerance, opioid withdrawal, or addictive behavior.

Cases of OIH have been reported, both with short-term and longer-term use of opioid analgesics. Though the mechanism of OIH is not fully understood, multiple biochemical pathways have been implicated. Medical literature suggests a strong biologic plausibility between opioid analgesics and OIH and allodynia. If a patient is suspected to be experiencing OIH, carefully consider appropriately decreasing the dose of the current opioid analgesic, or opioid rotation (safely switching the patient to a different opioid moiety) [see Dosage and Administration; Warnings and Precautions (5.15)].

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### 5.18 Hypoglycemia

Cases of methadone-associated hypoglycemia have been reported, some resulting in hospitalization. In many cases, patients had predisposing risk factors (e.g., diabetes). The relationship between methadone and hypoglycemia is not fully understood but may be dose dependent. If hypoglycemia is suspected, monitor blood glucose levels, and manage the patient as clinically appropriate.

## 6 ADVERSE REACTIONS

The following serious adverse reactions are described, or described in greater detail, in other sections:

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- Opioid-Induced Hyperalgesia and Allodynia [see Warnings and Precautions (5.8)]

*Hyperalgesia and Allodynia:* Cases of hyperalgesia and allodynia have been reported with opioid therapy of any duration [see Warnings and Precautions (5.8)].

*Hypoglycemia:* Cases of hypoglycemia have been reported in patients taking methadone [see Warnings and Precautions (5.18)].

## 9 DRUG ABUSE AND DEPENDENCE

### 9.1 Abuse

Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a healthcare provider or for whom it was not prescribed.

Abuse is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects.

Misuse and abuse of Methadone increase risk of overdose, which may lead to central nervous system and respiratory depression, hypotension, seizures, and death. The risk is increased with concurrent abuse of Methadone with alcohol and other CNS depressants. Abuse of and addiction to opioids in some individuals may not be accompanied by concurrent tolerance and symptoms of physical dependence. In addition, abuse of opioids can occur in the absence of addiction.

## 10 OVERDOSAGE

### Clinical Presentation

Acute overdosage with methadone can be manifested by respiratory depression somnolence progressing to stupor or coma.... Hypoglycemia...., and death.

בנוסף, בוצעו בעלון שינויי נוסח ועריכה.

למידע המלא יש לעיין בעלונים המפורסמים בצמוד להודעה זו.  
 העלונים פורסמו [במאגר התרופות של משרד הבריאות](#). ניתן לקבל העתק מודפס שלהם באמצעות פנייה לחברת מעבדות רפא בע"מ בטל': 02-5893939 או בכתובת דוא"ל [RA@rafa.co.il](mailto:RA@rafa.co.il).

בכבוד רב,

מעבדות רפא