

### **Morphine Martindale 10 mg/ml**

חברת אמ.בי.איי פארמה בע"מ מבקשת להודיע על עדכונים בעלון לצרכן (במתכונת עלון לרופא) של התכשיר שבנדון.

#### **התווית התכשיר:**

Symptomatic relief of moderate to severe pain, especially that associated with neoplastic disease, myocardial infarction, and surgery.

Pre-operatively as an adjunct to anesthesia for pain relief and to allay anxiety. Alleviation of the anxiety associated with severe pain. It is useful as a hypnotic where sleeplessness is due to pain.

morphine sulfate 10 mg/ml : **מרכיב פעיל:**

Solution for injection : **צורת המתן של התכשיר :**

אילו הם השינויים שנעשו בעלון לרופא:

- נמחק כל המידע הנוגע לתכשיר Morphine Martindale 20mg/ml, שכן תכשיר זה מעולם לא שווק ואינו מתוכנן להיות משווק בעתיד.
- נוסף black box, בהתאם להנחיית מחלקת רישום עבור תכשירים אופייטיים:

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

- Concomitant use of benzodiazepines other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death [see section 4.4].
- 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.

- נוספו עדכונים הכוללים החמרות. בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות **בצהוב**, מחיקת טקסט מסומנת בקו חוצה

#### **עדכונים בעלון נעשו בסעיפים הבאים**

#### **4.4 Special warnings and precautions for use**

[...]

##### **Opioid Use Disorder (abuse and dependence)**

Tolerance and physical and/or psychological dependence may develop upon repeated administration of opioids such as Morphine Martindale.

Repeated use of Morphine Martindale 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 Morphine Martindale 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).

Before and during treatment the patient should also be informed about the risks and signs of OUD. If these signs occur, patients should be advised to contact their physician.

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

[...]

#### **Sleep-related breathing disorders**

Opioids can cause sleep-related breathing disorders including central sleep apnoea (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.

#### **Severe cutaneous adverse reactions (SCARs)**

Acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, has been reported in association with morphine treatment. Most of these reactions occurred within the first 10 days of treatment. Patients should be informed about the signs and symptoms of AGEP and advised to seek medical care if they experience such symptoms.

If signs and symptoms suggestive of these skin reactions appear, morphine should be withdrawn and an alternative treatment considered.

[...]

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

[...]

Morphine should be used with caution in patients who are concurrently receiving other central nervous system depressants including sedatives or hypnotics, general anaesthetics, phenothiazines, other tranquilisers, muscle relaxants, antihypertensives, gabapentin or pregabalin and alcohol. Interactive effects resulting in respiratory depression, hypotension, profound sedation, or coma may result if these drugs are taken in combination with the usual doses of morphine.

#### **4.8 Undesirable effects**

[...]

##### **Gastrointestinal disorders:**

[...]

- Pancreatitis

##### **Reproductive system and breast disorders:**

[...]

- Central sleep apnoea syndrome

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://israeldrugs.health.gov.il/#!/byDrug>  
לחלופין, ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061, קדימה  
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