



ינואר 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת אי.אל.מדי-מרקט בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

## DEXMEDETOMIDINE KALCEKS 100 MCG/ML

### דקסמדטומידין קלצקס 100 מק"ג/מ"ל

חומר פעיל: DEXMEDETOMIDINE ( AS HYDROCHLORIDE ) 100 MCG /1 ML

צורת מינון: CONCENTRATE FOR SOLUTION FOR INFUSION

עדכונים בעלון לרופא

#### התוויה כפי שאושרה בתעודת הרישום:

For sedation of adult ICU (Intensive Care Unit) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale (RASS) 0 to - 3 ).

For sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation, i.e. procedural/awake sedation.

ברצוננו להודיע שהעלון לרופא עודכן. בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

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#### 4.4 Special warnings and precautions for use

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#### Other

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Diabetes insipidus has been reported in association with dexmedetomidine treatment. If polyuria occurs, it is recommended to stop dexmedetomidine and check serum sodium level and urine osmolality.

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#### 4.8 Undesirable effects

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#### Tabulated list of adverse reactions

The adverse reactions listed in Table 1 have been accumulated from pooled data of clinical trials in intensive care.



Adverse reactions are ranked under headings of frequency, the most frequent first, using the following convention: Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data).

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#### Endocrine disorders

Not known: Diabetes insipidus

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#### Renal and urinary disorders

Not known: Polyuria

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#### Description of selected adverse reactions

Clinically significant hypotension or bradycardia should be treated as described in section 4.4.

In relatively healthy non-ICU subjects treated with dexmedetomidine, bradycardia has occasionally led to sinus arrest or pause. The symptoms responded to leg raising and anticholinergics such as atropine or glycopyrrolate. In isolated cases bradycardia has progressed to periods of asystole in patients with pre-existing bradycardia. Also cases of cardiac arrest, often preceded by bradycardia or atrioventricular block, have been reported (see section 4.8).

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#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

<https://sideeffects.health.gov.il> ~~www.sideeffects.health.co.il~~

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העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות <https://israeldrugs.health.gov.il>.

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת אי.אל.מדי-מרקט בע"מ.