



אפריל 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

MIDAZOLAM KALCEKS 1 MG/ML

MIDAZOLAM KALCEKS 5 MG/ML

מידזולם קלצקס 1 מ"ג/ מ"ל

מידזולם קלצקס 5 מ"ג/ מ"ל

MIDAZOLAM 1 MG/ 1 ML חומר פעיל:

MIDAZOLAM 5 MG/ 1 ML

SOLUTION FOR INJECTION / INFUSION צורת מינון:

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Midazolam Kalceks is a short-acting sleep-inducing drug that is indicated:

In adults

- CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia

- ANAESTHESIA

- Premedication before induction of anaesthesia

- Induction of anaesthesia

- As a sedative component in combined anaesthesia

- SEDATION IN INTENSIVE CARE UNITS

In children

- CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia

- ANAESTHESIA

- Premedication before induction of anaesthesia

- SEDATION IN INTENSIVE CARE UNITS

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

4.8 Undesirable effects

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Table 4: Summary of adverse reactions

<i>Immune System Disorders</i>	
frequency not known	Hypersensitivity, angioedema, anaphylactic shock
<i>Psychiatric Disorders</i>	
frequency not known	Confusional state, disorientation, emotional and mood disturbances, changes in libido Physical drug dependence and withdrawal syndrome Abuse Paradoxical reactions* including; restlessness, agitation, irritability, nervousness, hostility, anger, aggressiveness, anxiety, nightmares, abnormal dreams, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects, paroxysmal excitement
<i>Nervous System Disorders</i>	
frequency not known	Involuntary movements (including tonic/clonic movements and muscle tremor)*, hyperactivity* Sedation (prolonged and postoperative), alertness decreased, somnolence, headache, dizziness, ataxia, anterograde amnesia**, the duration of which is directly related to the administered dose Convulsions have been reported in premature infants and neonates Drug withdrawal convulsions
<i>Cardiac Disorders</i>	
frequency not known	Cardiac arrest, bradycardia, Kounis syndrome****



*Such paradoxical drug reactions have been reported, particularly among children and the elderly (see section 4.4).

**Anterograde amnesia may still be present at the end of the procedure and in few cases prolonged amnesia has been reported (see section 4.4).

***There have been reports of falls and fractures in benzodiazepine users. The risk of falls and fractures is increased in those taking concomitant sedatives (including alcoholic beverages) and in the elderly.

**** Particularly after parenteral administration

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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 איי.אל.מדי-מרקט בע"מ.

