נובמבר 2018

רופא/ה נכבד/ה
רוקח/ת נכבד/ת

חברת תרו מבקשת להודיעכם כי העלונים לרופא של התכשירים Diprofol 1% amp and vials and Diprofol 2% vials עודכנו.

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלונים לרופא. תוספות סומנו בצבע אדום, המחיקות סומנו בצבע כחול ~~בקו מחיקה~~.
העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:
תרו אינטרנשיונל בע"מ, רחוב הקיטור 14, ת.ד 10347 מפרץ חיפה 2624761 .

בברכה,
מרינה גולדמן
רוקחת ממונה

Diprofol 1%, ampoules and vials

מרכיב פעיל:

Propofol 10mg/ml

ההתוויה המאושרת לתכשיר:

Diprofol 1% is a short-acting intravenous general anaesthetic for:

- induction and maintenance of general anaesthesia in adults and children > 1 month.
- sedation of ventilated patients >16 years of age in the intensive care unit.
- sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children > 1 month.

<u>עדכונים בעלון לרופא:</u>

4.4 Special warnings and precautions for use

The benefits and risks of the proposed procedure should be considered prior to proceeding with repeated or prolonged use (>3 hours) of propofol in young children (< 3 years) and in pregnant women as there have been reports of neurotoxicity in preclinical studies, see Section 5.3.

5.3 Preclinical safety data

Published studies in animals demonstrate that the use of anaesthetic agents during the period of rapid brain growth or synaptogenesis results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester through the first several months of life, but may extend out to approximately 3 years of age in humans.

In neonatal primates, exposure to 3 hours of an anaesthetic regimen that produced a light surgical plane of anaesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or

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longer increased neuronal cell loss. Data in foetal and neonatal rodents and primates suggest that the neuronal and oligodendrocyte cell losses are associated with subtle but prolonged cognitive deficits in learning and memory. The clinical significance of these preclinical findings is not known, and healthcare providers should balance the benefits of appropriate anaesthesia in young children less than 3 years of age and pregnant women who require procedures against the potential risks suggested by the preclinical data.

Diprofol 2%, vials

מרכיב פעיל:

Propofol 20mg/ml

ההתוויה המאושרת לתכשיר:

Diprofol 2% is a short-acting intravenous general anaesthetic for:

- induction and maintenance of general anaesthesia in adults and children > 3 years.
- sedation of ventilated patients >16 years of age in the intensive care unit.
- sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children > 3 years.

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In neonatal primates, exposure to 3 hours of an anaesthetic regimen that produced a light surgical plane of anaesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or longer increased neuronal cell loss. Data in foetal and neonatal rodents and primates suggest that the neuronal and oligodendrocyte cell losses are associated with subtle but prolonged cognitive deficits in learning and memory. The clinical significance of these preclinical findings is not known, and healthcare providers should balance the benefits of appropriate anaesthesia in young children less than 3 years of age and pregnant women who require procedures against the potential risks suggested by the preclinical data.

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