

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**. העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות: [www.health.gov.il](http://www.health.gov.il) וניתן לקבלם מודפסים 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:

Dipriferol 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.

### עדכונים בעלון לרופא:

#### 4.4 Special warnings and precautions for use

## Paediatric population

Diprolol 2% is not recommended for use in children < 3 years of age due to difficulty in titrating small volumes.

### Advisory statements concerning Intensive Care Unit management

Prescribers should be alert to these events in patients with the above risk factors and **immediately discontinue propofol when the above signs develop.**

## Additional Precautions

EDTA chelates metal ions, including zinc, and reduces microbial growth rates. The need for supplemental zinc should be considered during prolonged administration of Diprofol 1%, particularly in patients who are predisposed to zinc deficiency, such as those with burns, diarrhoea and/or major sepsis.

**תרו אינטרנשיונל בע"מ**

הקיסר 14,

ת.ד. 10347, מפרץ חיפה 2624761

טל : 04-8475700

04-8727165 : פקס



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

Lower doses of Diprofol 1% may be required where general anaesthesia is used as an adjunct to regional anaesthetic techniques. Profound **hypotension** has been reported following anaesthetic with propofol in patients treated with rifampicin.

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

Studies in animals have shown reproductive toxicity (see section 5.3).

#### 4.8 Undesirable effects

Reproductive system and breast disorders	Not known	Priapism
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### 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.

**עדכונים בעלון לרופא:**

#### Advisory statements concerning Intensive Care Unit management

Prescribers should be alert to these events in patients with the above risk factors and **immediately discontinue propofol when the above signs develop.**

#### Additional Precautions

EDTA chelates metal ions, including zinc, and reduces microbial growth rates. The need for supplemental zinc should be considered during prolonged administration of Diprofol 1%, particularly in patients who are predisposed to zinc deficiency, such as those with burns, diarrhoea and/or major sepsis.

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

Diprofol 2% has been used in association with spinal and epidural anaesthesia and with commonly used premedicants, neuromuscular blocking drugs, inhalational agents and analgesic agents; no pharmacological incompatibility has been encountered. Lower doses of Diprofol 2% may be required where general anaesthesia is used as an adjunct to regional anaesthetic techniques. Profound hypotension has been reported following anaesthetic with propofol in patients treated with rifampicin.

The concurrent administration of other CNS depressants such as pre-medication drugs, inhalation agents, analgesic agents may add to the sedative, anaesthetic and cardiorespiratory depressant effects of Diprofol 2% (see Section 4.4).

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

Studies in animals have shown reproductive toxicity (see section 5.3).

#### 4.8 Undesirable effects

Reproductive system and breast disorders	Not known	Priapism
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