

תאריך: דצמבר 2019

רופא/ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

## פרימן® 10 %

### PRIMENE® 10% Solution for Infusion

#### Contains:

Each liter of the infusion solution contains:

|                           |         |
|---------------------------|---------|
| L-Isoleucine              | 6.70 g  |
| L-Leucine                 | 10.0 g  |
| L-Valine                  | 7.60 g  |
| L-Lysine                  | 11.00 g |
| L-Methionine              | 2.40 g  |
| L-Phenylalanine           | 4.20 g  |
| L-Threonine               | 3.70 g  |
| L-Tryptophan              | 2.00 g  |
| L-Arginine                | 8.40 g  |
| L-Histidine               | 3.80 g  |
| L-Alanine                 | 8.00 g  |
| L-Aspartic Acid           | 6.00 g  |
| L-Cysteine                | 1.89 g  |
| L-Glutamic Acid           | 10.00 g |
| Glycine                   | 4.00 g  |
| L-Proline                 | 3.00 g  |
| L-Serine                  | 4.00 g  |
| L-Tyrosine                | 0.45 g  |
| L-Ornithine Hydrochloride | 3.18 g  |
| Taurine                   | 0.6 g   |

#### עדכונים בעלון לרופא

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#### התוויה כפי שאושרה בתעודת הרישום:

Primene 10 % is indicated in 1) children and infants 2) neonates at term or premature of normal or low birth weight when oral or enteral nutrition is impossible insufficient or contraindicated.

**ברצוננו להודיע שהעלונים עודכנו, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום):**

## **עדכונים בעלון לרופא:**

[...]

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

[...]

#### *Additional precautions*

• Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcomes in neonates, due to the generation of peroxides and other degradation products. When used in neonates and children below 2 years of age, Primene should be protected from ambient light until administration is completed (see sections 6.3, and 6.6).

[...]

### **6.3. Shelf Life**

The expiry date of the product is indicated on the packaging materials.

When used in neonates and children below 2 years of age, the solution (in bottles and administration sets) should be protected from light exposure until administration is completed (see sections 4.4 and 6.6).

[...]

### **6.6 Special precautions for disposal and other handling**

When used in neonates and children below 2 years of age, protect from light exposure until administration is completed. Exposure of Primene to ambient light, especially after admixture with trace elements and/ or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see sections 4.4 and 6.3).

**העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות**

**<http://www.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.**