

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

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, טקסט מחוק- בשחור עם קו מחיקה):

עדכונים בעלון לרופא:

4.2 Posology and method of administration

Posology

~~According to the child's weight, age and protein catabolism:~~

Parenteral nutrition initiation and duration as well as dosage (dose and rate of administration) depends on a patient's

- age, weight, clinical condition,
- nitrogen requirements,
- ability to metabolize the constituents of Primene,
- additional nutrition that may be provided parenterally and/or enterally.

The usual range is:

Posology		Maximal administration rate
<u>g/kg/day (24 hours)</u>	<u>ml/kg/day (24 hours)</u>	ml/kg/min
1.5 to 3.5 g of amino acids or 0.23 to 0.53 g of nitrogen	15 to 35	0.05

~~A too fast administration of amino acids may result in nausea, vomiting and tremors. In these cases, the infusion must be discontinued immediately.~~

The administration rate should never exceed 0.05 ml/kg/min.

Recommended flow rates ~~Duration and administration rate~~

Neonates and infants up to 2 years: continuous infusion (over 24 hours).

Children up to 12 years: - continuous infusion over 24 hours;

- cyclic infusion (over about 12 hours in 24) over approximately 12 hours.

The flow rate should be adjusted according to the dosage administration rate will depend on the posology, the characteristics of the infusion solution the solution infused, the total volume intake per 24 hours and the infusion duration.

The flow rate should be increased gradually during the first hour.

Method of administration

Primene is intended for intravenous use.

Primene is not intended for fluid or volume replacement.

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, 6.3 and 6.6).

Primene 10% is usually administered with ~~an energy supply~~ a source of energy that is adjusted to the child's needs, by co-administration or as a mixture.

Primene may be included in the composition of nutritive mixtures combining carbohydrates, lipids, electrolytes, trace elements and vitamins to meet nutrient needs and prevent deficiencies and complications from developing, when compatibility and stability are known (see section 6.2).

Routes of administration

Primene 10% alone: should be administered in a central vein ~~deep intravenous administration.~~

Primene 10% ~~by~~ in co-administration or as a mixture: should be administered according to the final osmolarity of the solution infused. ~~in a peripheral or central vein. superficial or deep intravenous administration.~~

The osmolarity of a specific infusion solution must be taken into account when peripheral administration is considered.

Strongly hypertonic parenteral nutrition solutions (>900 mOsm/L) should be administered through a central venous catheter with the tip located in a large central vein.

If deemed appropriate by the healthcare professional, parenteral nutrition solution may be administered peripherally in patients of all ages if the osmolarity of the formulation is ≤ 900 mOsm/L.

[...]

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
<http://www.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.