

פברואר 2021

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של

TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes

חומרים פעילים:

Composition of the reconstituted emulsion after mixing the contents of the 3 compartments:

Active substances	1500 ml	2000 ml
Refined olive oil+ refined soybean oil ^a	60.00 g	80.00 g
Alanine	9.61 g	12.82 g
Arginine	6.51 g	8.68 g
Aspartic acid	1.92 g	2.56 g
Glutamic acid	3.32 g	4.42 g
Glycine	4.60 g	6.14 g
Histidine	3.97 g	5.29 g
Isoleucine	3.32 g	4.42 g
Leucine	4.60 g	6.14 g
Lysine (equivalent to lysine acetate)	5.23 g (7.31 g)	6.97 g (9.75 g)
Methionine	3.32 g	4.42 g
Phenylalanine	4.60 g	6.14 g
Proline	3.97 g	5.29 g
Serine	2.62 g	3.50 g
Threonine	3.32 g	4.42 g
Tryptophan	1.10 g	1.47 g
Tyrosine	0.17 g	0.22 g
Valine	4.25 g	5.66 g
Sodium acetate, trihydrate	2.24 g	2.99 g
Sodium glycerophosphate, hydrated	5.51 g	7.34 g
Potassium chloride	3.35 g	4.47 g
Magnesium chloride, hexahydrate	1.22 g	1.62 g
Calcium chloride, dihydrate	0.77 g	1.03 g
Glucose anhydrous (equivalent to glucose monohydrate)	210.00 g (231.00 g)	280.00 g (308.00 g)

a: Mixture of refined olive oil (approximately 80%) and refined soybean oil (approximately 20%) corresponding to a ratio essential fatty acids / total fatty acids of 20%.

התוויה מאושרת:

TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes, emulsion for infusion is indicated for parenteral nutrition for adults and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.

עדכון העלון בעקבות שינוי בעל רישום לחברת Remedix Care Ltd.

להלן העדכון מסומן באדום והסרת מידע כטקסט מחוק:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the

National Regulation by using an online form <https://sideeffects.health.gov.il>

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

9. LICENSE HOLDER

~~Teva Medical Marketing~~ Remedix Care Ltd.

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העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות
www.health.gov.il וניתן לקבלם מודפסים על ידי פניה לחברת Remedix Care Ltd.

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