OLIMEL 7.6% and OLIMEL 7.6% E (containing 12 g Nitrogen/L) Injectable Emulsion

COMPOSITION
For OLIMEL **7.6%**: Active substances: Refined olive oil + refined soybean oil; Alanine; Arginine; Aspartic acid; Glutamic acid; Glycine; Histidine; Isoleucine; Leucine; Lysine; Methionine; Phenylalanine; Proline; Serine; Threonine; Tryptophan; Tyrosine; Valine; Glucose anhydrous.
For OLIMEL **7.6% E**: Active substances: Refined olive oil + refined soybean oil; Alanine; Arginine; Aspartic acid; Glutamic acid; Glycine; Histidine; Isoleucine; Leucine; Lysine; Methionine; Phenylalanine; Proline; Serine; Threonine; Tryptophan; Tyrosine; Valine; Sodium acetate, trihydrate; Sodium glycerophosphate, hydrated; Potassium chloride; Magnesium chloride, hexahydrate; Calcium chloride, dehydrate; Glucose anhydrous

Therapeutic indications

OLIMEL (amino acids WITH electrolytes, dextrose, lipids) or (amino acids, dextrose, lipids) is indicated for parenteral nutrition for adults when oral or enteral nutrition is impossible, insufficient or contraindicated.

Geriatrics: There are no known differences in safety and effectiveness of parenteral nutrition formulations in the adult population based upon age.

Pediatrics: There have been no studies performed in the pediatric population.

Contraindications: The use of OLIMEL is contra-indicated in the following populations/situations: Known hypersensitivity to egg, soybean products, olive products or any of the active substances, excipients, or components of the container. Known allergy to corn or corn products since the products contain corn-derived dextrose, patients with acute renal failure and without undergoing renal replacement therapy, patients with severe liver failure or hepatic coma, congenital abnormalities of amino acid metabolism, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia, hypertriglyceridemia-associated acute pancreatitis, severe hyperglycemia.

Additional contraindications specific to OLIMEL formulations with electrolytes: hyperkalemia, hypercalcaemia, hyperphosphatemia, hypernatremia, hypermagnesemia, ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including OLIMEL, through the same infusion line (e.g. via Y-site) because of the risk of precipitation of ceftriaxone-calcium salt.

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

The safety and clinical efficacy of OLIMEL (amino acids WITH electrolytes, dextrose, lipids) or (amino acids, dextrose, lipids) was assessed in a double-blind randomized controlled study over five days. Fifty-six (56) patients requiring parenteral nutrition were enrolled, of whom twenty-eight (28) were treated with OliClinomel (a triple-chamber parenteral nutrition product similar to OLIMEL, that contains the same olive oil/soybean oil lipid, a similar amino acid profile, and dextrose) and twenty-eight (28) were treated with OLIMEL. The goal of the study was to provide information on the safety and nutritional efficacy of OLIMEL in a clinical setting. A total of fifty-three (53) adverse events occurred during treatment; twenty-nine (29) adverse events were observed in fourteen (14) patients in the OLIMEL group versus twenty-four (24) adverse events observed in eleven (11) patients in the OliClinomel (control) group. Of the twenty-nine (29) adverse events observed in the OLIMEL group, seven (7) adverse events were designated as related to treatment. Of the twenty-four (24) adverse events observed in the OliClinomel (control) group, seven (7) patients presented with adverse events that were reported as related to treatment.

Summary of Treatment-Related Adverse Drug Reactions in the OLIMEL Study

System Organ Class	Adverse Event	Reported Incidence by Treatment Group			
		OLIMEL (n=28) up to 40 mL/kg/day		OLICLINOMEL (n=28) up to 40 mL/kg/day	
		N*	%	N*	%
Cardiac disorders	Tachycardia	1	3.57	0	0.00
Gastrointestinal disorders	Abdominal pain	1	3.57	0	0.00
	Diarrhea	1	3.57	1	3.57
	Nausea	1	3.57	0	0.00
Immune system disorders	Hypersensitivity	0	0.00	1	3.57
Investigations	Blood alkaline phosphatase increased	0	0.00	1	3.57
	Gamma-glutamyltransferase increased	0	0.00	1	3.57
Metabolism and nutrition	Decreased appetite	1	3.57	0	0.00

disorders	Hypertriglyceridemia	1	3.57	0	0.00
Renal and urinary disorders	Azotemia	0	0.00	1	3.57
Respiratory, thoracic and mediastinal disorders	Respiratory failure	0	0.00	1	3.57
Vascular disorders	Hemodynamic instability	0	0.00	1	3.57
	Hypertension	1	3.57	0	0.00

*Number of patients reporting the related event

Post-Market Adverse Drug Reactions

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Injection site extravasation, Pyrexia, Chills.

Class Reactions: The following adverse reactions have been reported with similar products: Pruritus, Fat overload syndrome, Cholestasis, Elevated liver enzymes and Azotemia. Pulmonary vascular precipitates (pulmonary vascular emboli and pulmonary distress).

For a detailed dosage and administration, warnings and precautions, interactions, clinical pharmacological and pharmaceutical particulars, please refer to the full Canadian product monograph. Medicinal products are subject to medical prescription. Revision date: June 2018