תאריך: 09.2020

רופא /ה, רוקח/ת נכבד/ה

<חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

ClinOleic® 20%, emulsion for intravenous infusion

Contains: ***שם וכמות החומר הפעיל***

Composition per 100 ml

20.00 g ..... Refined olive oil and refined soybean oil*

4.00 g ..... corresponding to a content of essential fatty acids

* Mixture of refined olive oil (approximately 80%) and refined soybean oil (approximately 20%)

עדכונים בעלון לצרכן / בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Source of lipids during parenteral nutrition in situations where oral or enteral feeding is impossible, insufficient or contra-indicated.

ברצוננו להודיע שהעלון לצרכן עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.3. Contra-indications

The use of ClinOleic is contra-indicated in the following situations:

- hypersensitivity to egg protein, soya protein or peanut protein or to any of the active substances or excipients
- severe hyperlipidaemia~~dyslipidemia~~ and severe disorders of lipid ~~non-corrected~~ metabolism ~~disorders including lactic acidosis~~ characterised by hypertriglyceridemia. Lipoid nephrosis and acute pancreatitis if accompanied by hyperlipaemia~~uncompensated diabetes~~.

4.4. Special warnings and precautions for use

WARNINGS

[…]

Patients at risk of refeeding syndrome include those with anorexia nervosa, chronic malnutrition (due to age or carcinoma), chronic alcoholism, prolonged fasting, or postoperative patients.

Baxter has not performed any compatibility studies of additions made directly to the ClinOleic 20% emulsion container. Destabilization of the lipid emulsion may result from such additions. If admixture into the ClinOleic 20% emulsion container is deemed necessary, insure that additives are compatible with the emulsion. Any additions to the container should be performed under strict aseptic conditions.

PRECAUTIONS

~~Hepatobiliary disorders~~Parenteral Nutrition Associated Liver Diseases (PNALD) including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The etiology of these disorders is~~n~~ thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, ClinOleic 20% should be protected from light until administration is completed (see sections 6.3 and 6.6).~~Use in paediatric population~~

~~ClinOleic 20% should be administered with caution in case of neonatal hyperbilirubinemia (total serum bilirubin > 200 µmol/l). Total bilirubin levels should be monitored closely.~~

~~As other lipid emulsions, ClinOleic 20% should be used in extremely premature and/or very low birth weight infant under the close supervision of a neonatologist. There is clinical experience for ClinOleic 20% infusion time, up to 7 days in neonates and up to 2 months in children.~~

4.8. Undesirable effects

[…]

Clinical Trial and Post-Marketing Adverse Drug Reactions Reported for ClinOleic 20%

BLOOD AND LYMPHATIC SYSTEM DISORDERS	Leukopaenia	Uncommon
	Thrombocytopaenia	Unknown
IMMUNE SYSTEM DISORDERS	Hypersensitivity	Unknown
METABOLISM AND NUTRITION DISORDERS	Hyperglycaemia	Common
	Hypoproteinaemia	Common
	Hyperlipidaemia†	Common
VASCULAR DISORDERS	Mean arterial pressure decreased	Common
	Circulatory collapse	Uncommon
	Hypotension	Uncommon
	Hot flush	Uncommon
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Dyspnoea	Uncommon
GASTROINTESTINAL DISORDERS	Nausea/Vomiting	Common
	Abdominal distension	Common
	Abdominal pain	Uncommon
	Epigastric discomfort	Uncommon
	~~Diarrhea~~	~~Unknown~~
HEPATOBILIARY DISORDERS	Cholestasis	Common
	Cytolytic hepatitis	Uncommon
	Cholecystitis	Unknown
	Cholelithiasis	Unknown

SKIN AND SUBCUTANEOUS DISORDERS	~~Urticaria,~~ Pruritus	Unknown
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Chills	Uncommon~~known~~
~~IMMUNE SYSTEM DISORDERS~~	~~Hypersensitivity~~	~~Unknown~~
INVESTIGATIONS	~~Mean arterial pressure decreased~~ ~~Bilirubin conjugated increased,~~ Blood bilirubin increased**	Common
	Liver function test abnormal[2]	Common
	~~Hepatic~~Pancreatic enzyme increased	Uncommon
	Blood triglycerides increased	Common
	~~International normalized ratio decreased~~	~~Unknown~~

Fat overload syndrome (very rare)~~:~~ see section 4.4 for more information.
During long-term parenteral nutrition, the following adverse reactions have been observed:

- increase of alkaline phosphatase, transaminases and bilirubin,
- rarely: hepatomegaly and icterus,
- moderate thrombocytopenia.~~Fat overload syndrome has been reported with similar products. Reduced ability to remove the lipids contained in ClinOleic 20% may result in a "fat overload syndrome", which may be caused by overdose, however, the signs and symptoms of this syndrome may also occur at the start of an infusion when the product is administered according to instructions. This syndrome is associated with a sudden deterioration in the patient's clinical condition as is characterised by hyperlipidemia, fever, liver fatty infiltration hepatomegaly, anemia, leukopenia, thrombocytopenia, coagulation disorders and coma, requiring hospitalization. These symptoms are usually reversible when the lipid emulsion infusion is stopped.~~

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, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see sections 4.4 and 6.6).

6.6. Instructions for use / handling and disposal
[...]

d. Administration

For single use only

After opening the bag, the contents must be used immediately. The opened bag must never be stored for a subsequent infusion. ~~Do not reconnect any partially used bag.~~

Use of a final filter is recommended during administration of all parenteral nutrition solutions, where possible.

Do not re-connect ~~any~~ partially used-bags.

Do not connect bags in series in order to avoid the possibility of air embolism due to air contained in the primary bag.

Air embolism can result if residual gas in the bag is not fully evacuated prior to administration if the flexible bag is pressurized to increase flow rates. Use of ~~a~~ vented intravenous administration set with the vent in the open position could result in air embolism.

~~Do not use the product if particles or agglomerates are observed in the solution.~~

Any unused product or waste material and all necessary devices must be discarded.

One litre containers are bulk source containers for pharmacy use and should not be used for direct intravenous infusion.

When used in neonates and children below 2 years, protect from light exposure, until administration is completed. Exposure of ClinOleic 20% to ambient light, especially if admixtures include trace elements and vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see sections 4.4 and 6.3).

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

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