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Clinolipid (Lipid Injectable Emulsion for Intravenous Use)

??? ??????: 30 ??????/?????? 2017

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The CLINOLIPID injection trials had small sample sizes and patients had a variety of underlying medical conditions both between different trials and within the individual trials. Patients had gastrointestinal diseases/dysfunction or were recovering from gastrointestinal or other surgeries, trauma, burns, or were afflicted by other chronic illness. The largest trial (Study 1, 48 subjects) enrolled patients with many different underlying diagnoses. The rates of treatment emergent adverse reactions can therefore not be directly compared to rates observed in the clinical trials of other related products and may not reflect the rates observed in clinical practice.

Commonly observed adverse reactions in 261 adult patients who received CLINOLIPID injection were nausea and vomiting, hyperlipidemia, hyperglycemia, hypoproteinemia and abnormal liver function tests and occurred in 2-10 % of patients. In Study 1 the most common adverse reactions were infectious complications (urinary tract infection, septicemia, and fever of unknown origin), treatment emergent abnormalities on liver/gallbladder ultrasound and abnormalities of serum chemistries, principally, hepatic function tests. Adverse reactions in Study 2 were similar.

Adverse reactions reported with other intravenous lipid emulsions include hyperlipidemia, hypercoagulability, thrombophlebitis, and thrombocytopenia.

Adverse reactions reported in long-term use with other intravenous lipid emulsions include hepatomegaly, jaundice due to central lobular cholestasis, splenomegaly, thrombocytopenia, leukopenia, abnormalities in liver function tests, brown pigmentation of the liver and overloading syndrome (focal seizures, fever, leukocytosis, hepatomegaly, splenomegaly and shock).

Post-marketing Experience

The following adverse reactions have been identified during use of CLINOLIPID injection, and listed by MedDRA System Organ Class, then by Preferred Term in order of severity. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

: Diarrhea**Gastrointestinal Disorders**

: Pruritus**Skin And Subcutaneous Tissue Disorders**

: International normalized ratio (INR) Decreased***Investigations**

*(In anticoagulated patients, CLINOLIPID injection may lower the INR)