Cerezyme® 30 YIL

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İmigluseraz Gaucher'de güvenli bir tedavidir.

Starzyk K et al. The long-term international safety experience of imiglucerase therapy for Gaucher disease. Mol Genet Metab 2007;90:157-63.

Background: Gaucher disease is a lysosomal storage disorder resulting from a deficiency of the lysosomal enzyme glucocerebrosidase. Since approval by the FDA in 1994 and EMEA in 1997, enzyme replacement therapy with Cerezyme® (imiglucerase for injection) has been the standard of care for the treatment of Gaucher disease.

Objective: To review the long-term international safety experience of imiglucerase from 1994 through 2004.

Materials and methods: All spontaneous adverse event reports captured in the pharmacovigilance database for imiglucerase from 1994 through 2004 were analyzed. All adverse events were classified using the current version of the Medical Dictionary for Regulatory Activities (MedDRA). Patients without prior exposure to imiglucerase from 1994 through 2005 were assessed for the development of antibodies to imiglucerase as detected by enzyme-linked immunosorbant and radioimmunoprecipitation assays.

Results: Analysis of the long-term safety experience with imiglucerase therapy demonstrates a stable and low rate of adverse events and seroconversion from 1994 through 2005. The majority of frequently reported adverse events related to imiglucerase were infusion-associated reactions which were predominantly self-limiting in nature and did not require discontinuation of treatment. Between 1994 and 2005, IgG antibodies to imiglucerase were detected in approximately 15% of treatment-naïve patients.

Conclusions: The long-term stability of reported events and seroconversion is a reflection of a well-characterized cell expression system and a mature quality-controlled manufacturing process. Imiglucerase is a safe therapy for the treatment of Gaucher disease with a stable and low rate of reported adverse events and seroconversion.

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