**Abcertin® (Imiglucerase for injection) 200 units**

**Description**

Abcertin® (imiglucerase for injection) is an analogue of the human enzyme β-D-glucosyl-N-acylsphingosine glucohydrolase (β-D-glucosyl-N-acylsphingosine glucohydrolase) is a lysosomal glycoprotein enzyme which catalyzes the hydrolysis of the glucosylated glycolipid to glucose and ceramide. The pathogenesis of Gaucher disease was identified as genetic mutations that cause deficiency of the enzyme activity of β-glucosidase, which is necessary in breakdown of the glucosylceramide into glucose and ceramide. The deficiency of the enzyme leads to the accumulation of the glucosylceramide in the lysosomes of macrophages. This accumulation again leads to symptoms such as anemia, thrombocytopenia, hepatomegaly, splenomegaly, bone crisis and neurological manifestations.

**Appearance**

White to off white lyophilized cake in colorless and transparent vial. After reconstitution colorless and clear liquid.

**Indication and Usage**

Abcertin® (imiglucerase for injection) is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of Type 1 Gaucher disease who show symptoms in one or more of the following conditions:
- anemia after exclusion of other causes, such as iron deficiency
- thrombocytopenia
- bone disease after exclusion of other causes such as Vitamin D deficiency
- hepatomegaly or splenomegaly

**Dosage and Administration**

Abcertin® (imiglucerase for injection) is administered by intravenous infusion over 1–2 hours. Dosage should be individualized to each patient. Initial dosages range from 2.5 mg/kg body weight 3 times a week to 60 mg/kg once every 2 weeks. Dosage should be individualized to each patient. Initial dosages range from 2.5 mg/kg body weight 3 times a week to 60 mg/kg once every 2 weeks. Dosages should be adjusted on an individual basis and may increase or decrease in order to achieve the optimal response to treatment. The current medical standards for emergency treatment are to be observed.

**Adverse Reactions**

Adverse reactions were reported as below in patients who were administered with Abcertin, in less than 1% of the patient population. Aseptic techniques should be used during pregnancy and the puerperium. This includes an increased risk of skeletal manifestations, exacerbation of cytopenias, haemorrhage, and an increased need for transfusion. Both pregnancy and lactation are known to stress maternal calcium homeostasis and to accelerate bone turnover. This may contribute to skeletal disease burden in Gaucher disease.

**Pregnancy and Lactation**

Abcertin® should be advised to consider commencing therapy prior to conception in order to attain optimal health. In women receiving Abcertin treatment discontinuation throughout pregnancy should be considered. Close monitoring of the pregnancy and clinical manifestations of Gaucher disease is necessary for the individualization of dose according to the patient's needs and therapeutic response.

**Special Precautions for Storage**

Store in a refrigerator (2 ~ 8 °C).

**Package**

200 Units/vial

**Market Authorization Holder**

**Manufacturer**

**Revision Date:** July 16, 2014