VPRIV® is a long-term enzyme replacement therapy (ERT) for patients with Gaucher disease. VPRIV is indicated for the improvement of symptoms of Gaucher disease (Anemia, thrombocytopenia, hepatomegaly and splenomegaly, and bone manifestation).[1]

VPRIV®*
velaglucerase alfa

VPRIV Abbreviated Prescribing Information

VPRIV® (Velaglucerase Alfa)
Abbreviated Prescribing Information
Before prescribing, please consult the Summary of Product Characteristics (SmPC).
Product Name: VPRIV 400 Units powder for solution for infusion. Indication: VPRIV is indicated for long-term enzyme replacement therapy (ERT) for paediatric and adult patients with Gaucher disease. **Dose and Administration:** VPRIV treatment should be supervised by a physician experienced in the management of patients with Gaucher disease. The reconstituted product is intended for intravenous infusion only. VPRIV is for single-use only and is administered through a 0.22 µm filter. Home administration under the supervision of a healthcare professional may be considered for patients who have received at least three infusions and were tolerating their infusions well. The recommended dose is 60 Units/kg administered every other week as a 60-minute intravenous infusion. Dose adjustments can be made on an individual basis based on achievement and maintenance of therapeutic goals. Clinical studies have evaluated doses ranging from 15 to 60 Units/kg every other week. Patients currently treated with imiglucerase enzyme replacement therapy for type 1 Gaucher disease may be switched to VPRIV, using the same dose and frequency. No dosage adjustment is recommended in patients with renal or hepatic impairment based on current knowledge of the pharmacokinetics and pharmacodynamics of Velaglucerase Alfa. Elderly patients may be treated with the same dose range (15 to 60 Units/kg) as other adult patients. Twenty of the 94 patients (21%) who received Velaglucerase Alfa during clinical studies were in the paediatric and adolescent age range (4 to 17 years). The safety and efficacy profiles were similar between paediatric and adult patients. Safety and efficacy in children below the age of 4 years have not yet been established, and no data are available. **Contraindications:** Severe allergic reaction to the active substance or to any of the excipients. **Warnings and Precautions:** *Hypersensitivity:* Hypersensitivity reactions have been reported in patients in clinical studies. Therefore, appropriate medical support should be readily available when Velaglucerase Alfa is administered. If a severe reaction occurs, current medical standards for emergency treatment are to be followed. Treatment should be approached with caution in patients who have exhibited symptoms of hypersensitivity to other enzyme replacement therapy. *Infusion-related reactions:* Infusion-related reactions were the most commonly observed adverse reactions in patients treated in clinical studies. Most of the infusion-related reactions were mild. The most commonly observed symptoms of infusion-related reactions were headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia/body temperature increased. In treatment-naïve patients, the majority of infusion-related reactions occurred during the first 6 months of treatment. *Prevention and management of infusion-related reactions, including hypersensitivity reactions:* The management of infusion-related reactions should be based on the severity of the reaction and include slowing the infusion rate, treatment with medicinal products such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. Pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions in those cases where symptomatic treatment was required. Patients were not routinely pre-medicated prior to infusion of Velaglucerase Alfa during clinical studies. *Immunogenicity:* Antibodies may play a role in treatment-related reactions found with the use of Velaglucerase Alfa. To further evaluate the relationship, in cases of severe infusion-related reactions and in cases of lack or loss of effect, patients should be tested for the presence of antibodies, and the results reported to the company. In the clinical studies, one of 94 (1%) patients developed IgG-class antibodies to Velaglucerase Alfa. No patients developed IgE antibodies to Velaglucerase Alfa. *Sodium:* This medicinal product contains 12.15 mg sodium per vial. This is equivalent to 0.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult. **Interactions:** No interaction studies have been performed. **Fertility, Pregnancy, and Lactation:** There are no or limited amount of data from the use of Velaglucerase Alfa in pregnant women. There is insufficient information on the excretion of Velaglucerase Alfa or its metabolites in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from VPRIV taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Animal studies show no evidence of impaired fertility. **Undesirable Effects:** The most serious adverse reactions in patients in clinical studies were hypersensitivity reactions (2.1%). The most common adverse reactions were infusion-related reactions (39.4%). *Very common (≥ 1/10):* Headache, dizziness, bone pain, arthralgia, back pain, infusion-related reaction, asthenia/fatigue, pyrexia/increased body temperature. *Common (≥1/100 to <1/10):* Hypersensitivity reactions (includes dermatitis allergic and anaphylactic/anaphylactoid reactions), tachycardia, hypertension, hypotension, flushing, nausea, rash, urticaria, activated partial thromboplastin time prolonged, neutralising antibodies positive abdominal pain/abdominal pain upper. **Marketing Authorisation Holder:** Shire Pharmaceuticals Ireland Limited, Block 2 & 3 Miesian Plaza 50-58 Baggot Street Lower, Dublin 2, Ireland. **Last updated: 02/01/2023**
Further information is available on request.

Suspected adverse reactions should be reported to Takeda, at: ae.middleeast@takeda.com.

Reference: 1. VPRIV SmPC Last Updated January 2023.

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PAAB
MEMBER OF INNOVATIVE MEDICINES CANADA

VPRIV velaglucerase alfa

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