Important Safety Information for Home Administration of VPRIV® (Velaglucerase Alfa for Infusion)

Indication

VPRIV® (velaglucerase alfa for infusion) is indicated for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease.

Adverse events

The most serious adverse reactions observed in patients treated with VPRIV® were hypersensitivity reactions. Appropriate medical support should be available when VPRIV® is administered. If a severe reaction occurs, medical standards for emergency treatment are to be followed.

Treatment with VPRIV® should be used with caution in patients who have exhibited symptoms of hypersensitivity to the active ingredient, drug product excipients, or to other enzyme replacement therapies.

Infusion-related reactions

An infusion-related reaction is any adverse drug reaction occurring within 24 hours after the initiation of the infusion. Most of the infusion-related reactions observed during the development of VPRIV® were mild. The most commonly observed symptoms of infusion-related reactions were: headache, dizziness, hypotension (low blood pressure), hypertension (high blood pressure), nausea, fatigue/weakness, and pyrexia (body temperature increased). In patients who had not used VPRIV® before, the majority of infusion-related reactions occurred during the first 6 months of treatment. Additional infusion-related reactions of chest discomfort, dyspnoea (difficulty breathing), and pruritus (severe skin itching) have been reported since VPRIV® was marketed.

Hypersensitivity

Hypersensitivity reactions, including symptoms consistent with anaphylaxis (severe allergic reaction), have been reported in patients using VPRIV®. The most frequently reported symptoms of hypersensitivity include nausea, rash, dyspnoea (difficulty breathing), back pain, chest discomfort, urticaria (hives), arthralgia (pain in the joints), and headache. If a patient experiences a reaction suggestive of hypersensitivity, subsequent testing for velaglucerase alfa antibodies is advised.

Management of infusion-related reactions

If an infusion-related reaction occurs, including a hypersensitivity reaction, discontinue the infusion immediately, assess the patient's condition, respond as per your local/facility protocol, and notify the physician.

Management of infusion-related reactions should be based on severity of the reaction, such as slowing the infusion rate, treatment with medications 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 is required. Patients were not routinely pre-medicated prior to infusion of VPRIV® during clinical studies.

Symptoms of Gaucher disease

Some general symptoms of Gaucher disease such as fatigue, weakness and lack of stamina, are similar to infusion-related reactions.

Your healthcare provider will explain to you how to tell normal symptoms and infusion-related reactions apart.

In general, fatigue, weakness and lack of stamina caused by an infusion-related reaction will occur in the 24 hours following the infusion and will be greater than usually experienced by the patient during the normal course of the disease.

If you are in any doubt contact your healthcare professional.

Further information

Refer to the VPRIV® SmPC and PIL for more information on product safety.

This checklist is intended for use in conjunction with the VPRIV® SmPC. This resource was developed by Shire as part of a commitment made in the Risk Minimisation Measures for VPRIV®. Please report any suspected adverse event(s) to the HPRA Pharmacovigilance, Earlsfort Terrace IRL – Dublin 2. Tel: +353 1 6764971 Fax: +353 1 6762517. Website: www.hpra.ie email: medsafety@hpra.ie and to Shire at globalpharmacovigilance@shire.com

IRE/EXA/GCB/16/0002 Date of preparation: June 2016

Emergency Plan for at Home Infusion of VPRIV® (Velaglucerase Alfa for Injection)

Necessary actions in the event of a serious infusion reaction:

1. Stop the infusion		☐
2. Call the national emergency number:	112	☐
3. Call the treating physician:		☐

Necessary actions in the event of a hypersensitivity reaction:

1. Stop the infusion	☐
2. Call the treating physician:	☐
3. If the homecare nurse is present, they will obtain a blood sample for antibody testing and store at 4ºC	☐
4. If the homecare nurse is present, they will arrange collection of the sample	☐

Adverse events should be reported. Adverse events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority (HPRA) at: www.hpra.ie/

Adverse events should also be reported to Shire Pharmaceuticals Ltd. on +44 (0)1256 894000 or faxed on +44 (0)1256 894715 or emailed to: globalpharmacovigilance@shire.com

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