הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 24/12/2015

שם תכשיר באנגלית ומספר הרישום VPRIV 146-02-33234-00

שם בעל הרישום מדיסון פארמה בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Hypersensitivity Hypersensitivity reactions, including symptoms consistent with anaphylaxis, have been reported in patients in clinical studies and in post-marketing experience. The majority of~~. As with any intravenous protein medicinal product,~~ hypersensitivity reactions usually occur up~~are possible. 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 12 hours post infusion. ~~be followed.~~ The most frequently reported ~~Treatment should be approached with caution in patients who have exhibited~~ symptoms of hypersensitivity include nausea, rash dyspnoea, back pain, chest discomfort (including chest tightness), urticaria, arthralgia, and headache. ~~to other enzyme replacement therapy.~~	Hypersensitivity Hypersensitivity reactions have been reported in patients in clinical studies. As with any intravenous protein medicinal product, hypersensitivity reactions are possible. 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	**4.4 Special warnings and precautions for use**

Infusion related-reactions An infusion-related reaction is defined as any adverse drug reaction occurring within 24 hours after the initiation of velaglucerase alfa infusion. Infusion-related reactions (IRR) were the most commonly observed adverse reactions in patients treated in clinical studies. An IRR often appears as a hypersensitivity reaction..~~Most of the infusion-related reactions were mild.~~ The most frequently reported~~commonly observed~~ symptoms of hypersensitivity include nausea, rash, dyspnoea, back pain, chest discomfort (including chest tightness), urticaria, arthralgia, and ~~infusion-related reactions were:~~ headache Symptoms consistent with anaphylaxis have been reported in patients in clinical studies and in post-marketing experience. Apart from symptoms associated with hypersensitivity reactions IRRs might show as fatigue, dizziness, ~~hypotension, hypertension, nausea, fatigue/asthenia, and~~ pyrexia, blood pressure increase or pruritus.~~/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. Due to the risk for hypersensitivity reactions including anaphylaxis appropriate medical support, including adequately	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. 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.

trained personnel in emergency measures, should be readily available when velaglucerase alfa is administered. If anaphylactic or other acute reactions occur, in the clinic or home setting, immediately discontinue the infusion and initiate appropriate medical treatment.
. For patients developing anaphylaxis in a home setting it should be considered to continue treatment in a clinical setting.

Treatment should be approached with caution in patients who have exhibited symptoms of hypersensitivity to velaglucerase alfa or other enzyme replacement therapy.

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.~~

Adverse reactions reported in patients with type 1 Gaucher disease are listed in Table 1. Information is presented by system organ class and frequency according to MedDRA convention. Frequency is defined as very common (≥1/10) and common (≥1/100 to <1/10). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. Adverse drug reactions derived from post-marketing reports other than interventional clinical trials are printed in italics

Table 1: Adverse reactions reported with VPRIV observed in patients with type 1 Gaucher disease. Italic text denotes post-marketing event.

System organ class	Adverse reaction	
	Very common	Common

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	Very common	Common

4.8

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך....27.12.2015

Immune system disorders		hypersensitivity reactions (includes dermatitis allergic and *anaphylactic*/anaphylactoid reactions)
Nervous system disorders	headache, dizziness	
Cardiac disorders		tachycardia
Respiratory, thoracic and mediastinal disorders		*dyspnea*
Vascular disorders		hypertension, hypotension, flushing
Gastrointestinal disorders	abdominal pain/abdominal pain upper	nausea
Skin and subcutaneous tissue disorders		rash, urticaria, *pruritus*
Musculoskeletal and connective tissue disorders	bone pain, arthralgia, back pain	
General disorders and administration site conditions	infusion-related reaction, asthenia/fatigue, pyrexia/body temperature increased	*Chest discomfort*
Investigations		activated partial thromboplastin time prolonged, neutralizing antibody positive

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