אפריל 2021

רופא/ה, רוקח/ת נכבד/ה,

הנדון: Vpriv 400 – עדכון עלון לרופא

חברת טקדה ישראל בע"מ מבקשת להודיעך על עדכון בעלון לרופא של התכשיר שבנדון.

התכשיר רשום בישראל להתוויה הבאה:

VPRIV is a hydrolytic glucocerebroside –□specific enzyme indicated for the long term replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease.

מרכיב פעיל: velaglucerase alfa 400u/vial

פרטי העדכון העיקריים הינם:

(טקסט שהושמט מסומן באדום עם קו חוצה, טקסט שנוסף מסומן בטקסט כחול, טקסט המהווה החמרה מודגש בצהוב)

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. The most frequently reported symptoms of hypersensitivity include nausea, rash, dyspnoea, back pain, chest discomfort (including chest tightness), urticaria, arthralgia, and 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, pyrexia, blood pressure increase, pruritus, ~~or~~ vision blurred, **or vomiting**. In treatment-naïve patients, the majority of infusion-related reactions occurred during the first 6 months of treatment.

...

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 **for Marketing Authorization** one of 94 (1%) patients developed IgG-class antibodies to velaglucerase alfa. In this one event, the antibodies were determined to be neutralising in an *in vitro* assay. ~~No infusion-related reactions were reported for this patient.~~ No patients developed IgE antibodies to velaglucerase alfa.
No infusion related reactions were reported.

Takeda Israel Ltd.
25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972-3-3733140 Fax (local) : + 972-3-3733150

Post-marketing phase

During a post marketing extension study, one patient developed IgG antibodies to VPRIV. In addition, a few events of positive neutralising antibodies and lack of effect were reported post marketing.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל העתק מודפס של העלון באמצעות פנייה לבעל הרישום:

טקדה ישראל בע"מ, רח' אפעל 25 , פתח-תקווה, טל': 03-3733140

בברכה,

טלי סרי
רוקחת ממונה
טקדה ישראל בע"מ

Takeda Israel Ltd.
25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972-3-3733140 Fax (local) : + 972-3-3733150