…

4.8 Undesirable effects

…

Description of selected adverse reactions

Vomiting

In some cases vomiting can be serious ~~(reported from post-marketing experience).~~ and severe. Vomiting most often occurs during the infusion and up to 24 hours after the infusion.

…

4.9 Overdose

There is limited information available regarding ~~no experience with~~ overdose ~~of~~ with velaglucerase alfa. In the majority of the cases reporting overdose, no additional adverse events were observed. However, in the event of accidental or intentional overdose, patients should be carefully observed and treatment should be symptomatic and supportive. There is no antidote available. The maximum dose of velaglucerase alfa in clinical studies was 60 Units/kg~~. S~~(see section 4.4).

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Reconstituted and diluted solution for infusion:

Chemical and physical in-use stability has been demonstrated for 24 hours at 2 °C to 8 °C under protection from light.

~~Use immediately. May be stored 24 hours at 2-8°c. Do not freeze.~~

From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and must not exceed 24 hours at 2 °C to 8 °C.

6.6 Special precautions for disposal and other handling

VPRIV requires reconstitution and dilution, and is intended for intravenous infusion only. ~~VPRIV~~ It is for single ~~-~~use only and is administered through a 0.22 µm filter.

Aseptic technique must be used~~Use aseptic technique~~.

VPRIV has to be prepared as follows:

~~Prepare VPRIV as follows:~~

1. The number of vials to be reconstituted is determined based on the individual patient's weight and the prescribed dose.

2. The required vials are removed from the refrigerator. ~~-~~Each 400 Units vial is reconstituted with 4.3 ml of sterile water for injections.

3. Upon reconstitution, ~~mix~~ vials **should be mixed** gently. **Vials should** ~~Do~~ not **be** shake**n**. Each vial will contain an extractable volume of 4.0 ml (100 Units/ml).

4. Prior to further dilution, ~~visually inspect the solution in the vials;~~ the solution **in the vials should be visually inspected; the solution** should be clear to slightly opalescent and colourless; ~~do not use if~~ the solution **should not be used if it** is discoloured or if foreign particulate matter is present.

5. The calculated volume of medicinal product is withdrawn from the appropriate number of vials and the total volume required is diluted in 100 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion. **The diluted solution should be** ~~M~~**m**ix**ed** gently. **It should** ~~Do~~ not **be** shake**n**.~~-~~ The infusion should be initiated within 24 hours from the time of reconstitution.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

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

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בברכה,

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