CSL Behring UK
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26 July 2024

Privigen (human normal immunoglobulin (IVIg)) 10% 50 mL: flakes reported in some batches of finished product.

Dear Healthcare Professionals,

CSL Behring in agreement with the European Medicines Agency and the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **During internal stability testing of Privigen® 10% 50 mL, it was discovered that certain batches exhibited flakes predominantly composed of IgG protein.**
- **The potentially affected batch is:**
  - **P100669778 exp. 31 Jan 2027**
- **As a precaution, vials from this batch should not be administered to patients; product replacement can be requested via your supplier's approved process.**
- **All other quality parameters conformed to the specified requirements.**
- **To date, no safety concern related to this quality defect has been identified.**

Background

Privigen is a normal human immunoglobulin product for intravenous use (IVIg). The solution is clear or slightly opalescent and colourless to pale yellow. It is indicated for replacement therapy in adults, children and adolescents (0-18 years) in:
– Primary immunodeficiency syndromes (PID) with impaired antibody production;
– Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of <4 g/l.

* PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines.

Privigen is also indicated for immunomodulation in adults, children and adolescents (0-18 years) in:
– Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count;
– Guillain-Barré syndrome;
– Kawasaki disease (in conjunction with acetylsalicylic acid);
– Chronic inflammatory demyelinating polyneuropathy (CIDP). Only limited experience is available of use of intravenous immunoglobulins in children with CIDP;
– Multifocal motor neuropathy (MMN).

The observation about the flakes, predominantly composed of IgG protein, in some batches was made during stability studies. IgG is the main component of Privigen, and as a precaution we ask that the affected batches are not administered to patients in case of any impact on efficacy and/or safety.

- **Potentially affected batch is:**
  - **P100669778 exp. 31 Jan 2027**

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Adverse events should also be reported to CSL Behring UK Ltd on 01444 447 405.

CSL Behring Company contact point:

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31-Jul-2024

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02-Aug-2024