<Date>

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 <National Competent Authority> 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.**
- **Potentially affected batches are:**
    - **P100518636 exp. 31 December 2025**
    - **P100520509 exp. 31 December 2025**
- **Vials from these batches should not be administered to patients; product replacement can be requested via usual channels.**
- **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 aggregation might have an impact on efficacy and/or safety.

The batches potentially affected by this issue are as follows:

Batch	Expiry date
P100518636 (CZ/HU)	31 Dec 2025
P100520509 (FR)	31 Dec 2025

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available. <include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Privigen 10% 50 mL Human normal immunoglobulin (IVIg)
Marketing authorisation holder(s)	CSL Behring GmbH
Safety concern and purpose of the communication	During internal stability testing of Privigen® 10% 50 mL, it was discovered that certain batches of the product exhibited flakes predominantly composed of IgG protein.
DHPC recipients	Hospital pharmacist and Healthcare professionals who received affected batches and who are administering the product to the patient. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	France, Czechia, Hungary

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	25 July 2024
Submission of translated DHPCs to the national competent authorities for review	01 August 2024
Agreement of translations by national competent authorities	08 August 2024
Dissemination of DHPC	22 August 2024