



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMADOC-1700519818-3028574
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Privigen

human normal immunoglobulin

On 23 April 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Privigen. The marketing authorisation holder for this medicinal product is CSL Behring GmbH.

The CHMP adopted a new indication as follows:²

Replacement therapy in adults, children, and adolescents (0-18 years) in:

- Primary immunodeficiency syndromes (PID) with impaired antibody production (see section 4.4).
- 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.

Measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (0-18 years) in whom active immunisation is contraindicated or not advised.

Consideration should also be given to official recommendations on intravenous human immunoglobulin use in measles pre-/post exposure prophylaxis and active immunisation.

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.

¹ Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold



- Guillain-Barré syndrome.
- Kawasaki disease (in conjunction with acetylsalicylic acid; see section 4.2.).
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). Only limited experience is available of use of intravenous immunoglobulins in children with CIDP.
- Multifocal motor neuropathy (MMN).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.