EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/CHMP/365308/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Flebogamma DIF

human normal immunoglobulin

On 27 June 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Flebogamma DIF. The marketing authorisation holder for this medicinal product is Instituto Grifols, S.A.

The CHMP adopted changes to the indications for Flebogamma DIF in line with the Guideline on core SmPC for human normal immunoglobulin for intravenous administration, which came into effect on 1 January 2019.

The full indications will therefore be as follows:[2]

"Replacement therapy in adults, children and adolescents (2 - 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**

- ~~Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed.~~
- ~~Hypogammaglobulinaemia and recurrent bacterial infections in plateau-phase multiple myeloma patients who failed to respond to pneumococcal immunisation.~~
- ~~Hypogammaglobulinaemia in patients after allogenic haematopoietic stem cell transplantation (HSCT).~~
- ~~Congenital AIDS with recurrent bacterial infections.~~

[1] Summaries 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, removed text as strikethrough

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Immunomodulation in adults, children and adolescents (2 - 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; see 4.2)**
- **Chronic inflammatory demyelinating polyradiculoneuropathy (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 in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.