26 February 2026
EMADOC-1700519818-3181751
Human Medicines Division

Final assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Privigen

Human normal immunoglobulin

Procedure no: EMA/PAM/0000319183

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

1. Introduction

On 10 December 2025, the MAH submitted a completed paediatric study for Privigen, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that study IgPro 10_5007 is a stand-alone study.

2.2. Information on the pharmaceutical formulation used in the study

Privigen was administered according to the labeling. No specific paediatric formulation was used.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

- IgPro 10_5007, General drug use-results survey for Privigen (chronic inflammatory demyelinating polyneuropathy, CIDP)

2.3.2. Clinical study

IgPro 10_5007 General drug use-results survey for Privigen in patients with CIDP

Description

Methods

Study participants

All patients with chronic inflammatory demyelinating polyradiculoneuritis (CIDP) received Privigen after the launch day at contracted medical institutions for the survey.

Treatments

Privigen was administered according to the labeling.

Objective

The objective of this survey was to examine the occurrence of hemolytic anemia as an ADR to Privigen. Observation period: 7 months.

Outcomes/endpoints

Occurrence of haemolytic anaemia during an observation period of 7 months.

Sample size

A total of 150 patients were registered across 32 hospitals by the end of this reporting period, respective CRFs were collected in 149 patients and fixed in 149 patients, too.

The safety analysis set included 149 patients with the fixed case report forms (CRFs).

Randomisation and blinding (masking)

N/A

Statistical Methods

Not provided.

Results

Patient characteristics

The number of males and females were 80/149 patients (53.69%) and 69/149 patients (46.31%), respectively, an age (median [range], hereinafter the same) was 60.0 (15 to 83) years, and a weight was 60.00 (34.9 to 93.0) kg. The reasons for Privigen use were "improvement of muscular weakness by CIDP" in 52/149 patients (34.90%), "preventing progress of decreased motor function by CIDP (in patients who showed improvement in muscular weakness)" in 69/149 patients (46.31%), and "improvement of muscular weakness by CIDP and preventing progress of decreased motor function by CIDP (in patients who showed improvement in muscular weakness)" in 28/149 patients (18.79%). The final diagnosis of 4 patients who administered Privigen for initial diagnosis of CIDP was amyotrophic lateral sclerosis (ALS), sensory neuropathy, elbow ulnar nerve disorder, and unknown, and these patients discontinued Privigen administration. In one patient who administered Privigen, the reason for Privigen use was determined to be for the treatment of CIDP symptoms of combined central and peripheral demyelination (CCPD).

The most common clinical disease type of CIDP was "typical CIDP" in 87/149 patients (58.39%). As for classified as atypical CIDP (n ≥5), "multifocal acquired demyelinating sensory and motor (MADSAM)" in 21/149 patients (14.09%), "pure motor" in 14/149 patients (9.40%), "distal acquired demyelinating symmetric (DADS)" in 13/149 patients (8.72%), and "unknown" in 9/149 patients (6.04%). The most common blood type was "blood type A" in 24/149 patients (16.11%), followed by "blood type O" in 18/149 patients (12.08%), "blood type B" in 10/149 patients (6.71%), "blood type AB" in 5/149 patients (3.36%), and "unknown" in 92/149 patients (61.74%). There were 110/149 patients (73.83%) treated with CIDP pre-treatment drugs, and the 5 most frequently used CIDP pre-treatment drugs were "Venoglobulin-IH" in 30/149 patients (20.13%), "Prednisolone" in 23/149 patients (15.44%), "Glovenin-I" in 20/149 patients (13.42%), "Kenketu Venoglobulin IH" in 17/149 patients (11.41%), and "Predonine" and "Kenketu Glovenin I" in 14/149 patients (9.40%) each.

There were 52/149 patients (34.90%) with medical history, and the most common medical history (n ≥5) by system organ class (SOC) was "neoplasms benign, malignant and unspecified (incl cysts and polyps)", "musculoskeletal and connective tissue disorders" and "injury, poisoning and procedural complications" in 10/149 patients (6.71%) each, followed by "infections and infestations" and "nervous system disorders" in 8/149 patients (5.37%) each, "gastrointestinal disorders" in 6/149 patients (4.03%), and "eye disorders" in 5/149 patients (3.36%).

There were 79/149 patients (53.02%) with complications, and the most common complication (n ≥5) by SOC was "metabolism and nutrition disorders" in 50/149 patients (33.56%), followed by "vascular disorders" in 32/149 patients (21.48%), "musculoskeletal and connective tissue disorders" in 17/149

patients (11.41%), "endocrine disorders" in 8/149 patients (5.37%), "gastrointestinal disorders" in 7/149 patients (4.70%), and "neoplasms benign, malignant and unspecified (incl cysts and polyps)" in 5/149 patients (3.36%). There were 53/149 patients (35.57%) treated with CIDP treatment-related concomitant drugs, and the 5 most frequently used CIDP treatment-related concomitant drugs were "Prednisolone" in 23/149 patients (15.44%), "Predonine" in 18/149 patients (12.08%), "Ciclosporin" in 7/149 patients (4.70%), and "Solu-Medrol" and "Methycobal" in 5/149 patients (3.36%) each. There were 3/149 patients (2.01%) treated with CIDP treatment-related combination therapy, of which the breakdown was "plasmapheresis", "occupational therapy", and "physical therapy and occupational therapy" in 1/149 patients (0.67%) each. The CIDP morbidity median period was 4.1834 (0.003 to 24.890) years.

Recruitment

In accordance with the indications of the drug "improvement of muscular weakness by CIDP" and "preventing progress of decreased motor function by CIDP in patients who showed improvement in muscular weakness", the general drug use-results survey was started on a central registration basis on 02 March 2020 and all CRFs were fixed on 16 May 2025.

Baseline data

The general drug use-results survey started on 02 March 2020, using a central registration method. A total of 33 sites were contracted for this survey. 150 patients were registered, and CRFs were collected for 149 patients. The number of patients included in the safety analysis set was 149.

• Sex: 80 males (53.7%), 69 females (46.3%)

• Age: Mean 57.0 years [SD 16.1, median 60.0 (range 15 to 83) years]

o <18 years: 1 (0.7%)

o 18 years or older: 148 (99.3%)

• Body weight (at the start of Privigen administration): Mean 60.6 kg [SD 12.7, median 60.0 (range 34.9 to 93.0) kg]

Number analysed

149 patients were included in the safety analysis set, one participant was 15 years old.

Efficacy results

N/A

Safety results

Among 149 patients included in the safety analysis set, Privigen initial dose per weight was 391.39 (267.0 to 740.7) mg/kg for 78 patients with reason for Privigen use at the initial dose "improvement of muscular weakness by CIDP". According to the medication package insert, as Privigen is administered on consecutive days via drip infusion when this drug used for "improvement of muscular weakness by CIDP", it was summed per a single unit of combined administration on consecutive days as 1 cycle and aggregated by cycle. Privigen initial dose by cycle per weight was 1,941.77 (401.9 to 3,703.7) mg/kg. Privigen average dose by cycle per weight was 1,915.76 (362.3 to 3,703.7) mg/kg for 80 patients including the patients with reason for Privigen use "Improvement of muscular weakness by CIDP". Privigen initial dose per weight was 975.61 (104.2 to 1,200.0) mg/kg for 71 patients with reason for

Privigen use at the initial dose "preventing progress of decreased motor function by CIDP (in patients who showed improvement in muscular weakness)". Privigen average 3-weekly dose per weight was 933.33 (239.2 to 24,230.8) mg/kg for 97 patients including the patients with reason for Privigen use "preventing progress of decreased motor function by CIDP (in patients who showed improvement in muscular weakness)". According to the medication package insert, as Privigen can be administered on consecutive days in divided doses when this drug used for "preventing progress of decreased motor function by CIDP (in patients who showed improvement in muscular weakness)", for the patients who received Privigen on consecutive days, it was summed per administration on consecutive days and aggregated as dose on consecutive days. Privigen total administration period as 27.14 (0.1 to 34.9) weeks in 149 patients included in the safety analysis Set.

By the end of this reporting period, 149 patients were included in the safety analysis set, including 107/149 patients (71.81%) who continued Privigen administration and 42/149 patients (28.19%) who discontinued Privigen administration.

In 149 patients included in the safety analysis set, none of the patients experienced a treatment-emergent adverse event of hemolytic anemia.

2.3.3. Discussion on clinical aspects

Study IgPro10_5007 was conducted in Japan to examine the occurrence of haemolytic anaemia as an adverse drug reaction to Privigen in the routine clinical practice in patients with CIDP. A total of 150 patients were enroled, CRFs were collected in overall 149 patients. One paediatric female 15-year-old patient was enrolled in this study. Privigen was administered intravenously to her at an initial dose of 400mL, with a total of 1 infusion during the observation period. No haemolytic anaemia was observed in any of the 149 patients included in the safety analysis Set, thus no new safety signals or concerns were identified in this survey regarding the use of Privigen.

3. CHMP overall conclusion and recommendation

The final results of study IgPro 10_5007, assessing the occurrence of haemolytic anaemia as an ADR to Privigen in 148 adult Japanese subjects and one adolescent Japanese study participant have been reported. No such ADR was reported during the observation period. The benefit-risk profile of Privigen remains unaltered. The MAH has not suggested any update to the Summary of Product Characteristics based on the performed study which is supported by the CHMP.

☒ **Fulfilled:**

No regulatory action required.