01/2026

רופא/ה, רוקח/ת נכבד/ה,

Kiovig קיוויג

Solution for I.V Infusion

תוספת התוויה CIDP והרחבת התוויה ל- SID

חברת **טקדה** שמחה לעדכן אודות אישור תוספת התוויה עבור חולי CIDP וכן אודות אישור להרחבת ההתוויה ל-SID.
העלון לרופא של התכשיר שבנדון עודכן בינואר 2026.

נוסח ההתוויה העדכני המאושר לתכשיר:

Replacement therapy in adults, and 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

Immunomodulation in adults, and 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; see 4.2).
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).

המרכיב הפעיל:

Human Normal Immunoglobulin 100mg/1ml

בעמוד הבא מפורטים השינויים העיקריים בעלון התכשיר. טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן בטקסט ~~אדום עם קו חוצה~~, טקסט המהווה החמרה מודגש בצהוב.

למידע נוסף, יש לעיין במאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל העתק מודפס של העלון באמצעות פנייה לבעל הרישום:

טקדה ישראל בע"מ, רח' אפעל 25 , פתח-תקווה, טל': 03-3733140

בברכה,

סיון לידאני ברג
רוקחת ממונה
טקדה ישראל בע"מ

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העדכונים העיקריים בעלון לרופא הינם:

4.1 Therapeutic indications

~~IVIg can be used in all age ranges, unless otherwise specified below~~
Replacement therapy in adults, and children and adolescents (0-18 years) in:

- ~~•~~ Primary immunodeficiency syndromes ~~(~~ (PID~~)~~) with impaired antibody production (see section ~~4.~~ 4.4).

~~• 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 have failed~~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 ~~respond~~mount at least a 2-fold rise in IgG antibody titre to pneumococcal ~~immunisation.~~

~~• Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT).~~

~~• Children and adolescents (age 0-18) with congenital AIDS~~polysaccharide and ~~recurrent bacterial infections.~~polypeptide antigen vaccines

Immunomodulation in adults, and 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; see 4.2).
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).

4.2 Posology and method of administration

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Posology

The dose and dose regimen ~~are~~ is dependent on the indication.

In replacement therapy the dose may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. Dose based on bodyweight may require adjustment in underweight or overweight patients.

The following dose regimens are given as a guideline.

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~~*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*~~
~~*to pneumococcal immunisation; children and adolescents with congenital AIDS and recurrent bacterial infections*~~
Secondary immunodeficiencies (as defined in 4.1.)

The recommended dose is 0.2-0.4 g/kg every three to four weeks.

~~*Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation*~~
~~The recommended dose is 0.2-0.4 g/kg every three to four weeks. The trough levels should be maintained above 5 g/l.~~
IgG trough levels should be measured and assessed in conjunction with the incidence of infection. Dose should be adjusted as necessary to achieve optimal protection against infections, an increase may be necessary in patients with persisting infection; a dose decrease can be considered when the patient remains infection free.

Primary immune thrombocytopenia

There are two alternative treatment schedules:

- 0.8-1~~-~~g/kg given on day one; this dose may be repeated once within 3 days
- 0.4 g/kg given daily for two to five days.

The treatment can be repeated if relapse occurs.

Guillain-Barré syndrome

0.4~~-~~ g/kg/day over~~-~~ 5~~-~~ days~~.~~ (possible repeat of dosing in case of relapse).
~~0.4 g/kg/day over 5 days.~~

Kawasaki Disease

~~1.6~~-2 ~~-~~g/kg should be administered ~~in divided doses over two to five days or 2.0 g/kg~~ as a single dose. Patients should receive concomitant treatment with acetylsalicylic acid.

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Starting dose: 2 g/kg divided over 2 -5 consecutive days

Maintenance doses:
1 g/kg over 1-2 consecutive days every 3 weeks.
The treatment effect should be evaluated after each cycle; if no treatment effect is seen after 6 months, the treatment should be discontinued.
If the treatment is effective long term treatment should be subject to the physicians discretion based upon the patient response and maintenance response. The dosing and intervals may have to be adapted according to the individual course of the disease.

The dose recommendations are summarised in the following table:

Indication	**Dose**	**Frequency of injections**

Replacement therapy in primary immunodeficiency	–starting dose: 0.4––0.8 g/kg maintenance dose: thereafter: 0.2––0.8 g/kg	every 3––4 weeks to obtain IgG trough level of at least 5––6 g/l
~~Replacement therapy in secondary immunodeficiency~~	~~0.2 – 0.4 g/kg~~	~~every 3 – 4 weeks to obtain IgG trough level of at least 5 – 6 g/L~~
~~Children and adolescents with AIDS~~	~~0.2 – 0.4 g/kg~~	~~every 3 – 4 weeks~~
~~Hypogammaglobulinaemia (< 4 g/L) in patients after allogeneic haematopoietic stem cell transplantation~~	~~0.2 – 0.4 g/kg~~	~~every 3 – 4 weeks to obtain IgG trough level above 5g/L~~
Replacement therapy in secondary immunodeficiency	0.2-0.4 g/kg	every 3-4 weeks to obtain IgG trough level of at least 5-6 g/l
Immunomodulation:		
Primary immune thrombocytopenia	0.8-1 g/kg or 0.4 g/kg/d	on day 1, possibly repeated once within 3 days for 2-5 days
Guillain-Barré syndrome	0.4 g/kg/d	for 5 days
Kawasaki disease	2 g/kg	in one dose in association with acetylsalicylic acid
Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)	starting dose 2g/kg maintenance dose: 1g/kg	In divided doses over 2-5 days every 3 weeks over 1-2 days
~~Immunomodulation:~~		
~~Primary immune thrombocytopenia~~	~~0.8 – 1 g/kg~~ ~~or~~ ~~0.4 g/kg/d~~	~~on day 1, possibly repeated once within 3 days~~ ~~for 2 – 5 days~~
~~Guillain-Barré syndrome~~	~~0.4 g/kg/d~~	~~for 5 days~~
~~Kawasaki disease~~	~~1.6 – 2 g/kg~~ ~~or~~ ~~2 g/kg~~	~~in divided doses for 2 – 5 days in association with acetylsalicylic acid~~ ~~in one dose in association with acetylsalicylic acid~~

Paediatric population

The posology in children and adolescents (0-18 years) is not different to that of adults as the

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posology for each indication is given by body weight and adjusted to the clinical outcome of the above mentioned conditions.

Hepatic impairment

No evidence is available to require a dose adjustment.

Renal impairment

No dose adjustment unless clinically warranted, see section 4.4.

Elderly

No dose adjustment unless clinically warranted, see section 4.4.

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