KAMADA
High Quality Pharmaceuticals

מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עידכון רישום כמפורט להלן, עבור התכשיר:

Megalotect CP; מגלוטקט CP

Solution for Infusion, IV

מרכיבים פעילים:

IMMUNOGLOBULIN NORMAL HUMAN (at least) 96 %
HUMAN PLASMA PROTEIN 50 MG/ML
CYTOMEGALOVIRUS ANTIBODY 100 U/ML

המאושר להתויה:

Prophylaxis of clinical manifestations of cytomegalovirus infection in patients subjected to immunosuppressive therapy, particularly in transplant recipients.
The concomitant use of adequate virostatic agents should be considered for CMV-prophylaxis.

מהות השינוי: עידכון בסעיפי ההתוויה ומשטר מינון (4.1,4.2) (הודגשו בצהוב).

בעלון חלו שינויים נוספים, העיקרי שבהם בסעיף 5.1 Pharmacodynamic properties

4.1 Therapeutic indications

Prophylaxis of clinical manifestations of cytomegalovirus infection in patients subjected to immunosuppressive therapy, particularly in transplant recipients.

The concomitant use of adequate virostatic agents should be considered for CMV-prophylaxis.

4.2 Posology and method of administration

Posology

The single dose is 1 ml per kg body weight.

Administration should be initiated on the day of transplantation. In case of bone marrow transplantation an initiation of prophylaxis up to 10 days before transplantation can also be envisaged, particularly in CMV sero-positive patients. A total of at least 6 single doses at 2 to 3 weeks' intervals should be given.

Paediatric population
The posology in children and adolescents (0-18 years) is not different to that of adults as the posology for each indication is given by body weight and adjusted to the clinical outcome of the above mentioned conditions.

Hepatic impairment

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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.

Method of administration
Intravenous use
Megalotect CP should be infused intravenously at an initial rate of 0.08 ml/kg BW/hr for 10 minutes. See section 4.4. In case of adverse reaction, either the rate of administration must be reduced or the infusion stopped. If well tolerated, the rate of administration may gradually be increased to a maximum of 0.8 ml/kg BW/hr for the remainder of the infusion.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל' 08-9406472).

להלן הקישור למאגר התרופות:

https://data.health.gov.il/drugs/index.html#/byDrug

בברכה,

צוות רישום קמהדע בע"מ

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