OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH

15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH Circular 44/2020
DH 550/2020

21st April 2020

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Change in brand of Human Normal Immunoglobulin Intravenous Injection

Human normal immunoglobulin intravenous injection is on the Hospital Formulary for in-patient use and can be prescribed by hospital doctors.

It is being brought to your attention that there is a change in brand of human normal immunoglobulin IV. The preparation currently available is Flebogamma DIF 50 mg/ml solution for infusion.

Flebogamma DIF is indicated for replacement therapy in adults, children and adolescents (2-18 years) who do not have sufficient antibodies. It is also indicated for immunomodulation in adults, children and adolescents (2-18 years) with 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, chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and multifocal motor neuropathy (MMN).

Flebogamma DIF does not contain sucrose, maltose or glucose. However, each ml of this medicinal product contains 50 mg of sorbitol. Patients with rare hereditary problems of fructose intolerance must not take this medicine.

As usual, the necessary precautions are to be taken when switching patients from one brand of human normal immunoglobulin to another. The following procedure should be followed:

1. For the first dose only, hydrocortisone is to be given as premedication.
2. When the switch occurs, the patient should be strictly monitored hourly during infusion and for at least 4 hours post-infusion before discharge.
3. Patients that are switched should be advised to monitor themselves for at least 2 days post-infusion and to report immediately any reactions or adverse effects.
4. Patients with renal or hepatic failure are at an increased risk of adverse reactions due to reduced clearance and extra caution should be taken when switching occurs. These patients should be monitored more closely and for 12 hours post-infusion. Patients due for switching are best advised in advance to prepare for the extended stay and change dates if this is not possible.
5. The emergency cart should be readily at hand during infusion and throughout the monitoring period.

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6. Patients should be called two days later to enquire about any adverse effects which may then need reporting.

The change in brand shall occur when the patients are called in for their scheduled treatment. Appointments are to be scheduled as early in the morning as possible.

If a patient makes an informed decision not to attend for treatment, this has to be documented. Treatment with human normal immunoglobulin IV should not be stopped unless requested by the caring physician.

Extra caution with switching is one time only when the switch occurs. Thereafter, normal monitoring as per usual schedule peri- and post-infusion should resume with subsequent doses.

Further information on Flebogamma DIF can be accessed here.

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

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