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CSL Biotherapies

Australian Red Cross BLOOD SERVICE

14 November 2011
Ref. CSL 2266

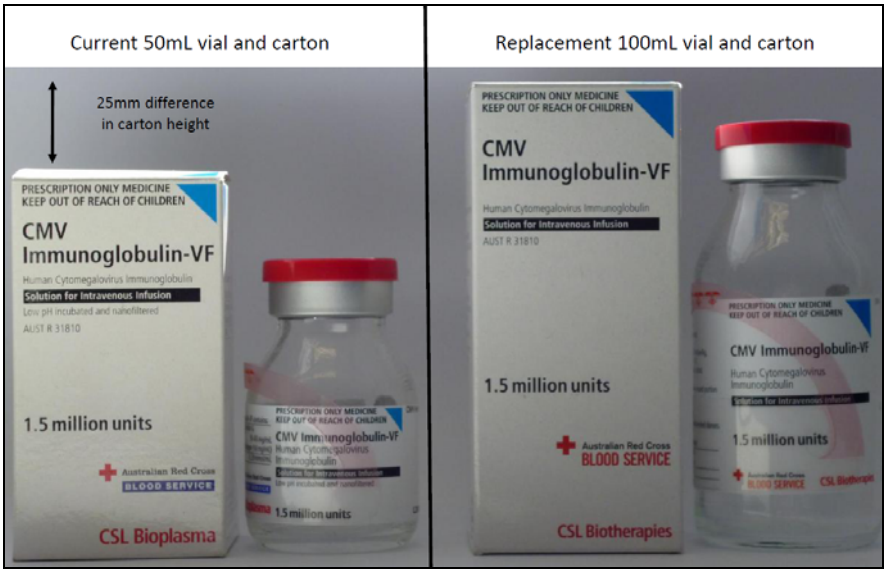
Dear Colleague,

Re: CMV Immunoglobulin-VF Shelf-Life Extension From 12 To 24 Months And Resultant Packaging Changes

As part of CSL Biotherapies' on-going commitment to enhance the utility of plasma-derived therapies fractionated under the Australian Fractionation Agreement, CSL Biotherapies announces the completion of all work necessary to extend the shelf-life of CMV Immunoglobulin-VF from 12 to 24 months.

Extension of the shelf-life to 24 months has been made possible through addition of a small overfill to each vial. As the potency of plasma from which this product is manufactured can vary, a 'potency fill' approach is used and hence the size of the overfill can vary. To ensure the required number of IU of product can always be accommodated in the vial, it has been necessary to change the vial used for CMV Immunoglobulin-VF from a 50mL, to a 100mL vial.

There is no change to the formulation of CMV Immunoglobulin-VF. Minor changes to the product label and carton design have been made at this time to align with CSL Biotherapies' updated packaging design. A photograph illustrating the changes appears below:



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The 24 month shelf-life and packaging changes will be effective for stock issued to the Australian Red Cross Blood Service from December 2011.

Yours sincerely,

Dr Elizabeth Campbell
Director, Commercial Operations
Plasma-Derived Therapies

Dr Joanne Pink
Chief Medical Officer
Australian Red Cross Blood Service

Before prescribing, please review the Approved Product Information available on request from CSL Biotherapies

PBS Information: This product is not listed on the PBS. These products are funded under arrangements implemented by the National Blood Authority. Please refer to the National Blood Authority for details

The Medicines Australia Code of Conduct defines standards for the content of materials produced, and the conduct of promotional activities undertaken, by pharmaceutical companies within Australia. As a member of Medicines Australia, CSL Biotherapies willingly complies with the Medicines Australia Code of Conduct (www.medicinesaustralia.com.au).

Minimum Product Information: CMV Immunoglobulin-VF (Human Cytomegalovirus Immunoglobulin, solution for intravenous injection). **Indications**: For the prevention of CMV infection in seronegative recipients of bone marrow and renal transplants from a CMV positive donor, and as an adjunct to therapy in patients with established CMV infection. **Contraindications**: Individuals who have had a true anaphylactic reaction to a human immunoglobulin product, and individuals with isolated IgA deficiency, unless they do not have circulating anti-IgA antibodies. **Precautions**: CMV Immunoglobulin-VF must only be administered intravenously. Administration may cause a precipitous fall in blood pressure and clinical picture of anaphylaxis. Infusion rate under 'Dosage & Administration' should be closely followed. Monitor patient's vital signs regularly during infusion. Adrenaline, oxygen, antihistamine and steroids should be available to treat acute anaphylactic reactions. Aseptic meningitis syndrome (AMS) may occur with high dose (2g/kg) IVIG treatment. Monitor patients for signs and symptoms of AMS. Renal dysfunction and acute renal failure may occur in high-risk patients. Adequately hydrate patients prior to infusion. Do not exceed recommended dose. Monitor renal function in at-risk patients and consider discontinuing infusion if renal function deteriorates. Safety and/or efficacy has not been established in pregnancy, lactation, the elderly or paediatric patients. CMV Immunoglobulin-VF is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors, and by dedicated virus removal and inactivation procedures included in the manufacturing process. Despite these measures, such products may still potentially transmit disease. Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate. For all precautions and risk factors, review approved PI. **Interactions**: CMV Immunoglobulin-VF may affect responses to live attenuated virus vaccines, and serological testing. The maltose present in CMV Immunoglobulin-VF may interfere with some blood glucose measurements (tests using glucose dehydrogenase), resulting in the overestimation of blood glucose results. Do not mix with other pharmaceuticals except as indicated. **Adverse Effects**: Reactions to IVIG tend to be related to the infusion rate and most likely occur in the first hour of infusion. Reactions may include abdominal pain, headache, flushing or pallor, chest tightness, dyspnoea, skin rash, itching, hypotension, nausea and vomiting. Delayed reactions may include chest pain, rigors or aching legs. Rarely, renal dysfunction, AMS and acute renal failure. Very rarely, true anaphylactic reactions such as urticarial, angioedema, bronchospasm or hypotension. Review approved PI. **Dosage & Administration**: As there is currently no international standard for CMV Immunoglobulin-VF, recommended dosage remains empirical. For prophylactic use, 25,000 u/kg on days -4, -2, on the day of transplantation (intra-operatively) and then weekly for two months. For therapy, 50,000 u/kg initially, repeated after 4-5 days and then every 10-14 days until clinical improvement observed. Infusion should be commenced at a rate of 1.0 mL/min. After 15 minutes increase slowly to maximum of 3-4 mL/min, over a further 15 minutes. If symptoms develop the infusion rate should be slowed or stopped temporarily. Contains no antimicrobial agent, use immediately after opening. Do not use if turbid. Based on CMV Immunoglobulin-VF Approved Product Information date of most recent amendment: 16 March 2011. (Version 09/11)