

Introduction of Flebogamma 5% DIF

Information for health professionals regarding patients who have previously received OCTAGAM and will now be supplied with Flebogamma 5% DIF

What is Flebogamma 5% DIF?

Flebogamma 5% DIF is an intravenous preparation of human immunoglobulin similar to Intragam P and OCTAGAM. It is manufactured by Instituto Grifols, S.A., Barcelona, Spain from the plasma of US donors collected at FDA accredited plasmapheresis centres. This product is registered by the Therapeutic Goods Administration (TGA) and is one of the intravenous immunoglobulin (IVIg) products included in the National Blood Authority (NBA) supply arrangements. Flebogamma 5% DIF is supplied in Australia by Lateral Grifols Pty Ltd.

Why does Australia import intravenous immunoglobulin?

In 2004 the NBA, on behalf of all Australian Governments, established a Standing Offer for a contingent supply of IVIg from overseas. The purpose of the Standing Offer is to provide access to an alternative, secure source of IVIg at a competitive price. This arrangement is in accordance with the primary policy objectives of government for the Australian blood sector, being:

- to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and
- to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

Reliance on voluntary, non-remunerated donations of whole blood and plasma and the promotion of national self-sufficiency are secondary policy government objectives.

Intragam P, manufactured by CSL Biotherapies from plasma collected from Australian voluntary non-remunerated blood donors, is the primary immunoglobulin product provided to meet the needs of the Australian public.

OCTAGAM 5% has been supplied under a contract with the NBA, and authorised and distributed by the Australian Red Cross Blood Service (Blood Service) under the national blood arrangements since 2004. These arrangements provide funding for supply of IVIg for clinical indications which meet the *Criteria for the clinical use of IVIg in Australia*.

Why is my patient receiving Flebogamma 5% DIF instead of OCTAGAM?

On 24 September 2010, Octapharma, following consultation with the TGA, initiated a precautionary voluntary recall of all batches of OCTAGAM distributed within Australia pending further investigation of increased overseas reports of thromboembolic episodes associated with the use of this product. It is unclear, at this time, how long the investigation will take. Further information regarding the recall of OCTAGAM can be obtained from the TGA website

(<http://www.tga.health.gov.au/alerts/medicines/octagam.htm>)

To ensure that Australia maintains adequate national reserves of IVIg during this time, governments have made a decision to increase supplies of an alternative imported IVIg product, Flebogamma 5% DIF, over the coming weeks.

My patient has been receiving OCTAGAM. What do I need to do?

Please refer to the Q&A Thromboembolic Adverse events related to Octagam document, prepared by Octapharma.

Is Flebogamma 5% DIF different to Intragam P or OCTAGAM?

All three products are similar.

Intragam P and Octagam have two viral inactivation/removal steps. Flebogamma 5% DIF has three viral inactivation/removal steps.

Plasma used for the manufacture for all three products is tested for hepatitis B, hepatitis C and HIV.

The stabiliser in Flebogamma 5% DIF is sorbitol. The stabiliser in Intragam P and Octagam is maltose.

A table comparing Intragam P, Flebogamma 5% DIF and OCTAGAM is provided in Appendix 1.

Is Flebogamma 5% DIF safe?

Flebogamma 5% DIF has been available on the international market since 1992, with over 40 million grams infused. There has not been any documented cases of viral transmission.

Flebogamma 5% DIF has been registered for use in Australia by the TGA. The TGA has assessed the variant Creutzfeldt-Jakob Disease (vCJD) and viral risk of Flebogamma 5% DIF and advises, based on a composite risk assessment taking into consideration both donor factors and manufacturing factors, that Flebogamma 5% DIF meets Australian safety standards as applied to Intragam P.

With any IVIg product, patients who have not previously received immunoglobulin therapy may experience a higher frequency of adverse events, including those of a minor nature. Side effects can be different in different people and so close monitoring and a slow infusion of the first dose of Flebogamma 5% DIF, as for any new IVIg preparation, is recommended even if a person has had previous treatment with Intragam P or OCTAGAM.

What are the clinical indications for Flebogamma 5% DIF?

Flebogamma 5% DIF is used for the same clinical indications as Intragam P and OCTAGAM in many countries around the world. Full indications can be reviewed in the Product Information and Consumer Medicine Information for Flebogamma 5% DIF and according to the Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia.

What are the side effects?

The side effects that are listed for Flebogamma 5% DIF are similar to those that are listed for Intragam P and OCTAGAM.

Not all side effects are experienced by everyone. They are often more common the first time you have an infusion. They can be related to how quickly the infusion is being given and may stop when the infusion is slowed.

Some side effects include; fever, chills, sweats, blue colour of the lips or fingers, pain or tightness in the chest, fast heart rate, tiredness, weakness or feeling generally unwell, headache, dizziness, nausea (feeling sick) or vomiting, feeling of heat in the face, skin reactions such as paleness, itching or eczema and muscle and back pain.

Patients should be advised to inform their nurse or doctor immediately if they experience:

- signs of allergy such as rash or hives on the skin, swelling of the face, lips, tongue or other part of the body
- shortness of breath, wheeze or trouble breathing
- severe dizziness, light headedness or fainting
- decreased urine output

These side effects may be serious but are rare. Patients should be advised to inform their nurse or doctor if they notice anything else that is making them feel unwell.