CSL Limited
189-209 Camp Road
Broadmeadows
Victoria 3047 Australia

T +613 9246 5200
F +613 9246 5299
www.csl.com.au

CSL Biotherapies

Australian Red Cross
BLOOD SERVICE

02 August 2011

OBSTETRICIAN/GYNECOLOGIST/MIDWIFE INFORMATION

Re: Supply of RHOPHYLAC (human Anti-D (Rh_o) immunoglobulin solution for injection)

Dear Health Care Professional,

In March 2011, the National Blood Authority approved the supply of RHOPHYLAC within Australia when access to an **intravenous** Rh (D) immunoglobulin product is required. RHOPHYLAC is indicated for use in large fetomaternal haemorrhage (FMH) where administration of intramuscular Rh (D) immunoglobulin is either contraindicated or not practical, or for inadvertent or emergency transfusion of Rh (D) positive blood to an Rh (D) negative female of childbearing potential. Previously, the intravenous Rh (D) immunoglobulin supply was ensured with the product WinRho-SDF (Baxter). The change over from WinRho-SDF to RHOPHYLAC will occur when current stocks of WinRho-SDF are depleted which is anticipated to occur during August 2011.

The introduction of RHOPHYLAC will not affect the current *Guidelines for the Prophylactic Use of Rh (D) Immunoglobulin (Anti-D) in Obstetrics.*[1,2] CSL Biotherapies Rh (D) Immunoglobulin-VF (for intramuscular administration) will remain the Rh (D) immunoglobulin product for all routine prophylaxis in pregnant women with Rh (D) negative blood group and no pre-existing anti-D antibodies.[1,2]

RHOPHYLAC is presented as a 1500 IU (300µg) pre-filled ready for use syringe. RHOPHYLAC is manufactured at CSL Behring AG Bern, Switzerland. It is manufactured from plasma collected from US donors at TGA and FDA approved blood centres.

The primary differences between WinRho-SDF and RHOPHYLAC are outlined in the following table.

Key presentation differences between WinRho-SDF and RHOPHYLAC

	WinRho-SDF[3]	RHOPHYLAC[4]
Strength	600 IU / 120µg	1500 IU / 300µg
Presentation	One vial of sterile freeze dried gamma globulin fraction and one vial of diluent, reconstituted to between 1.25-2.5mL for intravenous injection.	Glass syringe pre-filled with 2mL solution for injection
Dose in FMH	- 100 IU (20µg) WinRho-SDF/mL Rh (D) positive red cells - A 600 IU (120µg) vial will suppress the immunising potential of <6mL of Rh(D) positive red cells - Maximum dose 3000 IU q8h IV	- 100 IU (20µg) RHOPHYLAC/mL Rh (D) positive red cells - A 1500 IU (300µg) vial will suppress the immunising potential of <15mL of Rh (D) positive red cells. - Maximum dose 15,000 IU (3000µg), independent of whether the transfusion volumes are >300mL of Rh (D) positive blood
Administration (Intravenous)	- 1.25mL - 2.5mL (480 IU/mL – 240 IU/mL) injected into a suitable vein at a rate of 1500 IU over 5-15 seconds - within 72 hours of complication	- 2mL (1500 IU) per 15-60 seconds[5] - within 72 hours of complication

One introductory batch of RHOPHYLAC (Batch 4345200052) will be supplied with the English version of the International packaging (carton, label and Package Insert) for a short time period due to the need to ensure continuity of supply of intravenous Rh (D) immunoglobulin. CSL Biotherapies have received an exemption from the TGA to import RHOPHYLAC with the English International packaging. It is anticipated that RHOPHYLAC with the Australian approved packaging and Product Information will be supplied towards the end of 2011. The RHOPHYLAC batch supplied with the English

International packaging is the same product as that which will be supplied with Australian packaging.

The main difference between the RHOPHYLAC English International packaging and the Australian approved packaging is the way the dose is presented. The dose on the English International packaging is expressed as 300µg, whereas it is 1500 IU on the Australian approved packaging. A 300µg dose is equivalent to 1500 IU. The indications, dosing and administration instructions are the same for both versions of the product.

RHOPHYLAC has a shelf life of 3 years (36 months) when stored at 2-8°C. The pre-filled syringe format offers optimum convenience for administration.

For any further information on RHOPHYLAC, please see the attached *Frequently Asked Questions about the use of* RHOPHYLAC or refer to the Product Information[4].

RHOPHYLAC can be accessed via the Australian Red Cross Blood Service.

Yours sincerely,

Dr Darryl Maher
Senior Director, Medical and Research
CSL Biotherapies

Dr Joanne Pink
Chief Medical Officer
Australian Red Cross Blood Service

References:

1. National Blood Authority Guidelines on the prophylactic use of Rh (D) immunoglobulin (anti-D) in obstetrics. June 2003
2. Rh (D) Immunoglobulin-VF Approved Product Information. Date of most recent amendment 07 December 2007
3. WinRho SDF Product Information. Date of most recent amendment 06 May 2010
4. RHOPHYLAC Product Information. Date of TGA approval 01 September 2009
5. RHOPHYLAC U.S. Package Insert. Date of Initial US Approval 2004. Revised 09/2010