April 23, 2012

Subject: Important treatment advance in Transfusion Medicine – Octaplasma® is now available in Canada

Dear Health Care Professional,

Octapharma is pleased to announce that Canadian patients will now have access to Octaplasma®, which comes to Canada with 20 years of safety and clinical experience in Europe.

Octaplasma® is pharmaceutically licensed, pathogen-inactivated plasma for transfusion. Octaplasma® (Solvent Detergent Treated Fresh Frozen Plasma - formerly known as Octaplas®) will be made available through Canadian Blood Services (CBS) shortly. The risk of an emerging pathogen affecting blood products and the need to protect the blood supply from such emerging agents using available pathogen reduction technologies has been well discussed.¹ We are happy to play our part to add to the safety and security of blood products in Canada.

Octaplasma® was developed as a standardised, Health Canada licensed biopharmaceutical (drug), to meet the following needs:

(a) Prevent viral transmissions by inactivating highly infectious enveloped² and non enveloped viruses

(b) Meet the demand for a cell free, standardised and high quality coagulation-active plasma for infusion, which is in good haemostatic balance, in order to
   - Reduce Adverse Events linked to residual blood cells
   - Standarise levels of coagulation factors to improve therapeutic accuracy and efficacy through better planning and monitoring of treatment

(c) Prevent other Adverse Events by dilution/neutralisation of allergens/soluble substances and antibodies against white blood cells: TRALI

How is Octaplasma® produced: A short summary

High quality US FFP units that are NAT tested for HIV, Hepatitis A, Hepatitis B, Hepatitis C and Parvovirus B19 are pooled in batches (≈ 1500 units). Through pooling, antibodies to white cells are diluted and neutralised, which significantly reduces the risk for TRALI, the most serious transfusion complication resulting in death⁵. Efficient, multiple size exclusion filtration procedures ensure all
cells and cell debris are removed (1.0 → 0.2 μm) to reduce adverse events. The plasma pool is virus inactivated by the solvent/detergent (S/D) process, which destroys viruses with a lipid envelope such as HIV, HBV and HCV. Non-enveloped viruses such as Hepatitis A and Parvovirus B19 are eliminated by immune neutralisation to meet stringent release criteria. Further sterile filtration takes place before filling 200ml bags. The production procedure ensures that each unit of Octaplasma® is standardised with respect to volume and as well as content of coagulation factors.

Octaplasma®: Global experience

Octaplasma® has been in continuous clinical use for over two decades in major European and other markets with over 7.3 million infusions in 2.4 million patients. Both in clinical trials and in clinical practice, the efficacy of Octaplasma is deemed comparable to FFP and Cryo Poor Plasma (CPP)⁴. Through very large national pharmacovigilance databases, an 84% decrease in adverse events⁵ have been observed and most recently the 2010 UK Serious Hazards of Transfusion (SHOT)⁶ database reported no occurrence of allergic reactions with Octaplasma.

Octaplasma®: Availability in Canada

Effective April 1st 2012, the provincial/territorial deputy ministers of health have approved the distribution of Octaplasma® through CBS, which will be made available for the following patients who require a high volume of transfusion due to:

1. Congenital and acquired Thrombotic thrombocytopenic purpura (TTP)
2. Haemolytic Uremic Syndrome (HUS)
3. Complex and isolated coagulation disorders – both congenital and acquired – where no specific coagulation factor concentrate is available

And who:
- Have experienced an allergic reaction to frozen plasma (FP), or
- Have a pre-existing lung disorder, or
- Need FP but a blood group compatible product is not available in a timely manner

Storage and Handling⁶:

Octaplasma® is frozen at -30⁰ C and can be stored at -18⁰ C for four years. Administration of Octaplasma® must be based on ABO-blood group compatibility. In emergency cases, Octaplasma® blood group AB can be regarded as universal plasma since it can be given to all patients. Octaplasma® must be administered by intravenous infusion after thawing using an infusion set with a filter. Thawed Octaplasma® must not be refrozen. Unused product must be discarded.
Request more information or an inservice:

To request additional information or an inservice, please send an email with your request in the subject line to info@octapharma.ca

We remain confident that Octaplasma®, through this demonstrated experience, will contribute to the safety and security of our transfusion practices, both of which serve as the foundation to our blood system.

Sincerely,

Sri Adapa
General Manager
Octapharma Canada Inc

Notice: Please refer to the full prescribing information available through our med info service or online at www.octapharma.ca

About TTP: TTP is a rare, but life threatening disease that usually involves an abnormality of a recently discovered enzyme known as ADAMTS-13. This enzyme controls the activity of a plasma protein called von Willebrand factor (VWF), which is responsible for helping platelets to stick at a wound site and plug the hole in the blood vessel. If the activity of VWF is too high and uncontrolled, blood platelets tend to stick together in places where they are not required, which can cause clumps of platelets in the capillaries. This results in thrombosis, red blood cell damage, lysis and tissue injury.

References: