

May 26<sup>th</sup>, 2014

Dear Healthcare Professional,

### **Reconstitution of octaplex®**

Please find below some information regarding what to do should you experience ineffective reconstitution of octaplex® using the Mix2Vial®.

The octaplex® product kit contains the following: vial-containing powder (octaplex®), vial-containing diluent (Water for injection), transfer set (Mix2Vial®) and package inserts (consumer information and instructions for reconstitution). During reconstitution, the blue spike of the Mix2Vial® is inserted into the rubber stopper of the diluent vial, then the system is inverted and the other spike of the Mix2Vial® is inserted into the rubber stopper of the powder vial – the diluent is then drawn into the powder vial by vacuum.

It is important that the vials are held firmly on a flat surface when the Mix2Vial® spike is inserted into the rubber stopper of the product vials. It is also important that the vials (both the contents and the vials themselves, including the rubber stoppers) and the transfer set (Mix2Vial®) are at room temperature before and during the reconstitution. At low temperatures (e.g. 5°C / refrigerator temperature), when the blue spike of the Mix2Vial® is inserted into the rubber stopper of the WFI vial, a small slit could be created in the rubber stopper, thereby allowing air to enter the vial (and causing a loss in vacuum in both the WFI vial and the octaplex® vial). Typically this results in approximately half of the WFI (i.e. 10 mL of the 20 mL) being transferred to the powder vial, with the other remaining 10 mL remaining in the diluent vial.

Based on internal testing, we had previously concluded that: “if the octaplex® vials are at room temperature prior to and during reconstitution, no loss of vacuum should occur.”

However, recently we have begun to receive feedback from hospitals describing situations of ineffective reconstitution of octaplex® even when all vials are at or close to, room temperature.

Should you experience such a loss of vacuum and ineffective reconstitution of octaplex®, we recommend that you take the following steps:

1. Firmly hold the transparent and blue parts of the Mix2Vial®. Unscrew the Mix2Vial® into two separate pieces with the vials still attached. The WFI vial and the blue end of the Mix2Vial® should still at this stage be connected and form one piece.

2. Separate the blue end of the Mix2Vial® from the WFI vial.
3. Separate the transparent end of the Mix2Vial® from the octaplex® vial.
4. Disinfect the stoppers of the diluent and the product vials.
5. Take a plastic sterile disposable syringe and, using an aseptic technique, draw any diluent remaining in the WFI vial, into the syringe.
6. Transfer the diluent from the syringe directly into the octaplex® vial.
7. Re-attach the transparent end of the Mix2Vial® to the octaplex® vial.
8. Slowly rotate the octaplex® vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. The reconstitution should be done in a gentle manner, with only gentle swirling of the solution. Vigorous shaking should be avoided. This is common practice not only for coagulation factor concentrates, but also for all protein solutions.
9. Attach a new, plastic, sterile, disposable luer-lock syringe to the transparent end of the Mix2Vial® and draw the reconstituted octaplex® solution into the syringe (note: the transparent end of the Mix2Vial® contains an integrated filter).

Should you require further assistance, please communicate with Medical Affairs at 1 416 531 5533, or visit our website at [www.octapharma.ca](http://www.octapharma.ca). Thank you for your interest in the octapharma products.

Cordially,

Dr. David G. Barnes  
BSc BMedSc MD  
Medical Director  
Octapharma Canada