

Instructions for reconstitution:



1. Warm the octaplex[®] powder and water for injection (WFI) in the closed vials up to room temperature (maximum 37°C). This temperature should be maintained during reconstitution.



Fig. 1

2. Remove the flip caps from the octaplex[®] vial and the WFI vial and clean the rubber stoppers with an alcohol swab.



Fig. 2

3. Peel away the lid of the outer package of the Mix2Vial™ transfer set. Place the WFI vial on an even surface and hold the vial firmly. Take the Mix2Vial™ together with its outer package and invert it. Push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the WFI vial (Fig. 1). While holding onto the WFI vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the WFI vial (Fig. 2).



4. With the octaplex[®] vial held firmly on an even surface, quickly invert the WFI vial (with the Mix2Vial™ attached) and push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the octaplex[®] vial (Fig. 3). The WFI will be drawn into the octaplex[®] vial by vacuum.



Fig. 3

5. With both vials still attached, slowly rotate the octaplex[®] vial to ensure the product is fully dissolved to a clear or slightly opalescent solution. Once the contents of the octaplex[®] vial are dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces with the vials still attached (Fig. 4) and discard the empty WFI vial and the blue part of the Mix2Vial™.



Fig. 4

6. Attach a plastic sterile disposable 20 mL syringe to the transparent part of Mix2Vial™. Invert the system and draw the reconstituted octaplex[®] into the syringe.
7. Once the octaplex[®] solution has been transferred into the syringe, firmly hold the barrel of the syringe (keeping it facing down) and detach the Mix2Vial™ from the syringe. Discard the Mix2Vial™ (transparent plastic part) and the empty octaplex[®] vial.