

## CSL BEHRING: HUMATE-P (Factor VIII/Von Willebrand Factor Complex, Human)

HUMATE P, Antihemophilic Factor/Von Willebrand Factor Complex, Human, indicated in adult and pediatric patients with von Willebrand disease for (1) treatment of spontaneous and trauma-induced bleeding episodes and (2) prevention of excessive bleeding during and after surgery. This applies to patients with severe VWD as well as patients with mild to moderate VWD where use of desmopressin is known or suspected to be inadequate.

Humate-P is purified from the cold insoluble fraction of pooled human fresh frozen plasma and contains highly purified and concentrated Antihemophilic Factor/von Willebrand Factor Complex (Human). Humate-P has a high degree of purity with a low amount of non-factor proteins.

Humate P is supplied in a single dose vial with a vial of diluent, Mix2Vial™ filter transfer set and alcohol swabs. International unit activity of Factor VIII and VWF:RCo is stated on the carton and label of each vial and supplied in three potencies, low, mid and high. It has a small infusion volume (5 – 15 mL diluent), meaning patients can administer their therapy conveniently and quickly. When stored up to 25°C (up to 77°F), Humate P is stable up to the expiration date printed on its label. Avoid freezing.

### Contraindications to the use of Humate P:

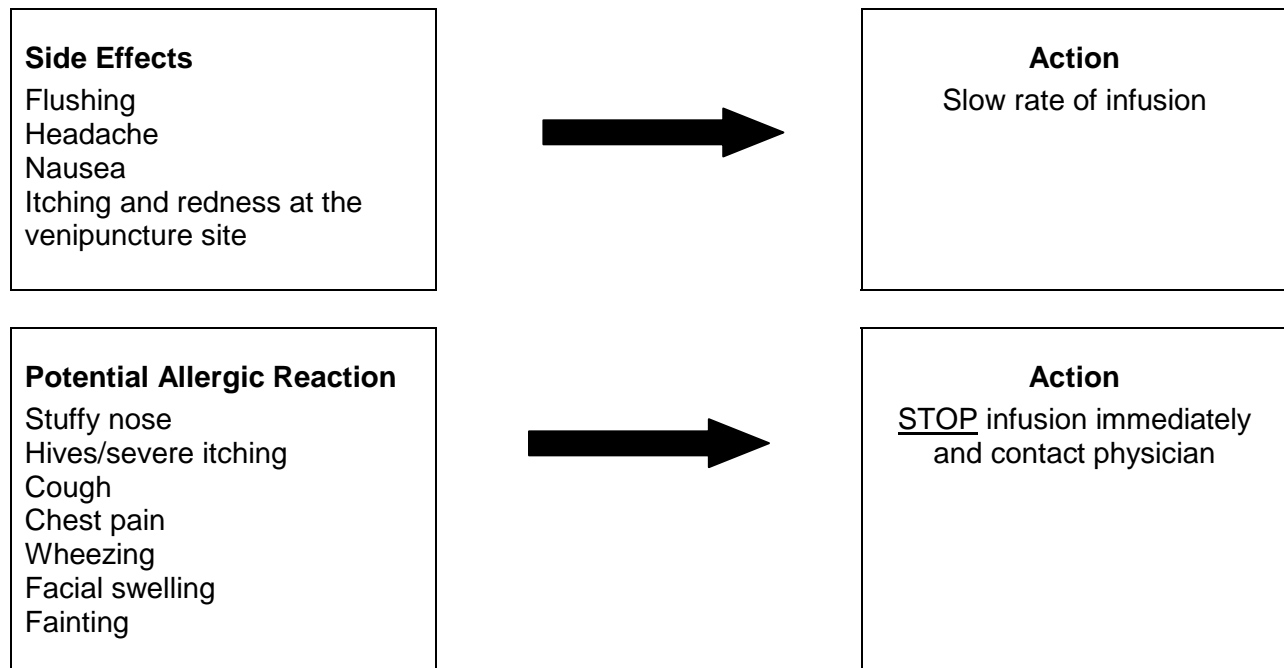
Known hypersensitivity to antihemophilic factor or von Willebrand factor preparations.  
Known intolerance or allergic reaction to any of the constituents in the formulation of Humate P.

### WARNINGS

Thromboembolic events have been reported in VWD patients receiving coagulation factor replacement therapy, especially in the setting of known risk factors for thrombosis. In these patients, caution should be exercised and antithrombotic measures should be considered.

### Side Effects:

Although few adverse reactions have been reported in clinical studies and in the post marketing setting in patients receiving Humate-P for treatment of VWD, the most commonly reported are allergic-anaphylactic reactions (including urticaria, chest tightness, rash, pruritus, edema, and shock).



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### **STEP 1**

Bring Humate P to room temperature (NOT >37°C). Choose a clean, dry, well-lit work area.

#### Contained in Box

- Bottle(s) of factor powder (lyophilized)- check dose & expiry date
- Bottle(s) of sterile water (diluent)
- Mix 2Vial™ (blue)

#### Packaged Separately

- Alcohol swabs
- Sterile plastic Luer Lock syringe

### **STEP 2**

Wash hands, under nails and forearms

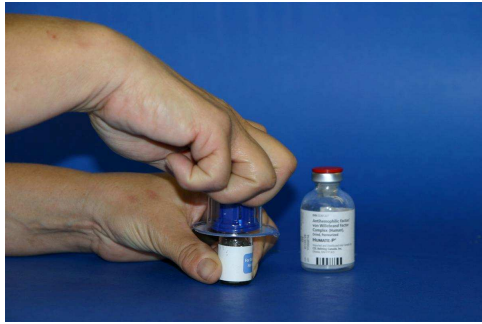
- Use warm running water
- Use antibacterial soap from pump dispenser
- Dry hands with a paper towel
- Turn off taps with paper towel & discard

### **STEP 3**

Remove the caps from the bottle(s) of factor powder and sterile water.

### **STEP 4**

Clean the tops of the bottles with an alcohol swab. Allow to dry completely. **DO NOT** blow on the tops to speed up drying, this will contaminate them.



### **STEP 5**

Open the Mix 2Vial™ package by peeling away the lid without touching the inside of the package. To maintain sterility, leave the Mix2Vial™ in the clear outer packaging. Place the diluent vial on an even surface and hold the vial tight. Grip the Mix2Vial™ together with the clear packaging and firmly snap the blue end onto the bottle of sterile water



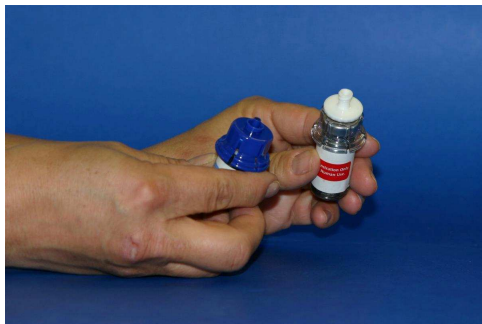
### **STEP 6**

While holding onto the diluent vial, carefully remove the clear outer packaging from the Mix2Vial™ set. Make sure that you only pull up the clear outer packaging and not the Mix2Vial™ set.



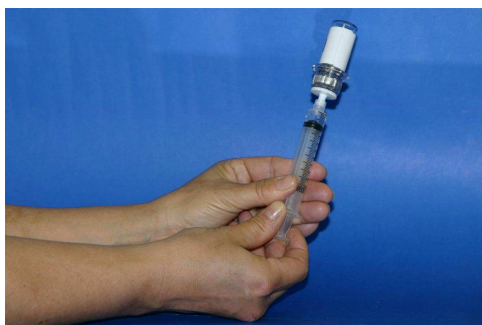
### **STEP 7**

With the product vial firmly on a surface, invert the diluent vial with set attached and firmly snap the transparent adapter onto the product vial stopper. The diluent will automatically transfer into the product vial. With the diluent and product vial still attached, gently swirl the product vial to ensure the product is fully dissolved. Do not shake vial.



### **STEP 8**

With one hand grasp the product-side of the Mix2Vial™ set and with the other hand grasp the blue diluent side of the Mix2Vial™ set and unscrew the set into two pieces .

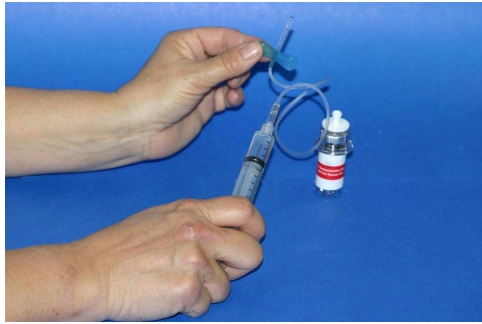


### **STEP 9**

Draw air into an empty, sterile syringe. While the product vial is upright, screw the syringe to the Mix2Vial™ set. Inject air into the product vial. While keeping the syringe plunger pressed, invert the system upside down and draw the concentrate into the syringe by pulling the plunger back slowly

### **STEP 10**

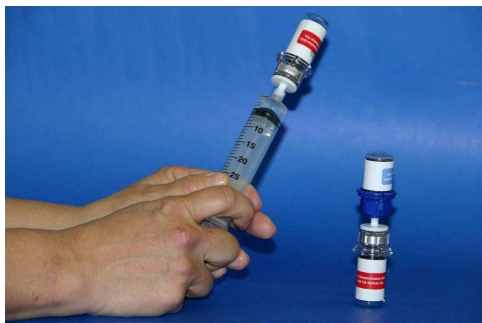
Now that the concentrate has been transferred into



**Peripheral Vein**



**Port**



the syringe, firmly grasp the barrel of the syringe (keep the syringe plunger facing down) and unscrew the syringe from the Mix2Vial™. Attach the syringe to a butterfly infusion set. Holding the syringe and needle pointing up, gently flick the syringe to move any air bubbles to the top and gently push on the plunger to remove the air. DO NOT push any factor solution out of the syringe.

#### **STEP 11**

Attach a blunt fill needle for PORT infusion Mark the syringe with a piece of tape if using PORT.

#### **MULTIVIAL DOSE**

#### **STEP 12**

Mix all product vials, using a new Mix2Vial™ set for each vial, as directed in Step 1 – 8 to prepare the prescribed dose to the nearest vial. Select a syringe large enough to hold the prescribed dose.

#### **STEP 13**

Follow Step 9 to draw the product from each vial into the larger syringe. Go to Step 10 for administration using a butterfly infusion set or Step 11 for administration through an established peripheral IV or Port-a-Cath®.

**ADMINISTER SLOWLY (THROUGH PERIPHERAL VEIN OR PORT-A-CATH®) AT A RATE NOT MORE THAN 4 ML PER MINUTE (i.e. 10 ML OVER 2.5 MINUTES). DISPOSE OF BUTTERFLY NEEDLE OR WINGED INFUSION SET IN SHARPS CONTAINER, REMAINDER OF WASTE TO BE DISPOSED OF IN HOUSEHOLD GARBAGE.**

<http://www.lhsc.on.ca/lab/bldbank/assets/BTRManual.pdf>