FACTOR VIII WITH VON WILLEBRAND FACTOR (HUMAN)

(Humate-P®; Wilate®; FVIII/vWF)

CLASSIFICATION

- Antihemophilic Factor/von Willebrand Factor Complex (Human) Dried, Pasteurized

INDICATIONS

- Von Willebrand disease: for adults and pediatrics: 1) treatment and prevention of spontaneous and traumatic bleeding episodes unresponsive to desmopressin therapy or if contraindicated; 2) for prevention or treatment of excessive bleeding during or after surgery.
- Hemophilia A: treatment and prophylaxis of bleeding in adult patients with congenital or acquired Factor VIII deficiency.

ADMINISTRATION

- Each vial contains the labelled amount of Factor VIII (FVIII) activity expressed in international units (IU) for the treatment of haemophilia A; as well as von Willebrand Factor: Ristocetin Cofactor (vWF:RCof) activity expressed in IU for the treatment of von Willebrand disease.

Humate-P®:

- Available in vials containing nominal concentrations of FVIII 250 IU / vWF:RCof 600 IU; FVIII 500 IU / vWF:RCof 1200 IU; and FVIII 1000 IU / vWF:RCof 2400 IU
- Reconstitute as per package insert using the supplied diluent and needless transfer device.
- IV Direct: physician or RHCP; at a maximum rate of 4 mL/minute.

Wilate®:

- Available in vials containing nominal concentrations of FVIII 500 IU / vWF:RCof 500 IU; and FVIII 1000 IU / vWF:RCof 1000 IU.
- Reconstitute as per package insert using the supplied diluent and transfer set.
- IV Direct: physician or RHCP; at a slow rate (2-3 mL/minute).

POTENTIAL ADMINISTRATION HAZARDS

- Hypersensitivity: rash, urticaria, pruritus, angioedema, wheezing, chest tightness, hypotension, anaphylaxis.
- Cardiovascular: edema (facial and peripheral), thrombotic events.
- GI: nausea, vomiting.
- CNS: dizziness, headache.
- Paresthesia, chills.
- Risk of transmission of infectious agents, including viruses, and theoretically, the Creutzfeldt-Jakob disease agent, cannot be completely eliminated as product is made from pooled human plasma.
- Local reactions: pruritus and pain at injection site.

DOSAGE

- Refer to product monographs.
- Dose is ordered in Factor VIII activity expressed in IU for the treatment of hemophilia A and in vWF:RCof activity expressed in IU for the treatment of von Willebrand Disease.
  The ratio of FVIII to vWF:RCo in Humate-P® is approximately 1:2.4
  The ratio of FVIII to vWF:RCo in Wilate® is approximately 1:1

COMPATIBILITY, STABILITY

Humate-P®:

- Store vials at 2-25°C. Avoid freezing (may damage the diluent container).
- Do not refrigerate after reconstitution. To assure product sterility, Humate-P® should be administered within 3 hours after reconstitution.

Wilate®:

- Store vials between 2-8°C. Protect from light. Do not freeze.
- May be stored at room temp (maximum 25°C) for up to 6 months. If stored at room temp, the vial must be used within 6 months, or discarded.
- After reconstitution the solution should be used immediately.

MISCELLANEOUS

- Refer also to the Factor VIII (recombinant) monograph for products that do not contain vWF.

AVAILABILITY

- Factor VIII with von Willebrand Factor (Human) is available from the Blood Bank.

REFERENCES

5, 40, 135.

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