**DESCRIPTION**

Antihemophilic Factor (Human) Koâ¬åte-DVI is a sterile, stable, purified, and concentrated human Antihemophilic Factor (AHF) 8%-10%.[1] It is a glycoprotein expressed in the plasma of healthy donors and is purified from plasma by a specific sequence of steps including affinity chromatography and ion exchange chromatography. The final product when reconstituted as directed contains not more than (NMT) 1500 µg/mL polyethylene glycol (PEG) PEG 1500, sodium phosphate, 200–400 mg/L (NMT) 150 µg/mL aluminum, 4–10 mg/mL bovine albumin, and 100–150 µg/mL surfactants (PG/CH). It is a sterile, powder, dried, lyophilized product. Koâ¬åte-DVI is intended for use in therapy of classical hemophilia (hemophilia A).

**CLINICAL PHARMACOLOGY**

Hemophilia A is a hereditary bleeding disorder characterized by deficient coagulant activity of the specific plasma protein clotting factor VIII. Without treatment, hemorrhages may occur spontaneously or after minor trauma or surgery on such individuals is not bleed well without first correcting the clotting abnormality. The administration of Koâ¬åte-DVI provides an increase in plasma levels of factor VIII and can temporarily correct the coagulation defect in these patients.

**DOSAGE AND ADMINISTRATION**

Koâ¬åte-DVI is indicated for the treatment of classic hemophilia A (hemophilia A) in which a deficiency of activity of the plasma clotting factor VIII is present. It is not indicated for von Willebrand's disease.

**PRECAUTIONS**

Koâ¬åte-DVI has not been investigated for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.

Koâ¬åte-DVI has not been approved for efficacy in the treatment of von Willebrand's disease, and hence is not approved for such usage. Koâ¬åte-DVI contains naturally occurring von Willebrand's factor, which is co-purified as part of the manufacturing process.
For 6 months, such as in home treatment situations, may be done without loss of factor VIII activity. Freezing should be avoided as breakage of the concentrate vial, directing the stream of fluid against the wall of the concentrate vial.


10. Eyster ME, Bowman HS, Haverstick JN: Adverse reactions to factor VIII infusions. [letter]


**Dosage**

**Factor VIII concentrate** may also be administered on a regular schedule for prophylaxis of bleeding as reported by Nakou et al.13 Incorrect diagnosis, inappropriate dosage, method of administration, and biological differences in individual patients, could reduce the efficacy of this product or even result in an adverse effect. In all cases, it is important that the product be stored properly, handled correctly and be used according to the recommendations of the manufacturer. The in vivo percent elevation in factor VIII level can be estimated by multiplying the dose of AHF (H) per kilogram of body weight (IU/kg) by the factor VIII level. Therapy need not be repeated unless there is evidence of further bleeding.

1. After removing all items from the box, wash the sterile water (diluent) to room temperature (25°C, 77°F).

2. Remove shrink band from product vial.

3. Label the filter needle (from the package) to a sterile syringe. Withdraw the Koate-DVI solution into the syringe through the filter needle (Fig. A). This will establish the right concentration of factor VIII in the syringe.

4. Remove the filter needle from the syringe and replace with an appropriate injection or butterfly needle for administration. Discard filter needles in a puncture proof container, and new equipment should be used.

5. Carefully grip the shaft of the other end of the transfer needles and twist to remove it.

6. Insert the diluent vial and insert the attached needles into the vial at a 45° angle (Fig. C). This will direct the stream of diluent against the wall of the concentrate vial and remove foam. The foam will then be drawn into the concentrate vial (Fig. D). Remove the concentrate vial, directing the stream of fluid against the wall of the concentrate vial.

7. Remove the concentrate bottle and transfer needle (Fig. E). Immediately after adding the diluent, vigorously agitate for 10-15 seconds (Fig. E) then store continually until completely dispensed (Fig. E). Some foaming will occur; but attempt to avoid excessive foaming. The solution should then be visually inspected for particulate matter and discoloration prior to administration.

8. Place the concentrate bottle in a warm place and protect it from light. The concentrate bottle should be kept in a warm place and protected from light.


10. Eyster ME, Bowman HS, Haverstick JN: Adverse reactions to factor VIII infusions. [letter]


**Dosage**

**Factor VIII concentrate** may also be administered on a regular schedule for prophylaxis of bleeding as reported by Nakou et al.13 Incorrect diagnosis, inappropriate dosage, method of administration, and biological differences in individual patients, could reduce the efficacy of this product or even result in an adverse effect. In all cases, it is important that the product be stored properly, handled correctly and be used according to the recommendations of the manufacturer. The in vivo percent elevation in factor VIII level can be estimated by multiplying the dose of AHF (H) per kilogram of body weight (IU/kg) by the factor VIII level. Therapy need not be repeated unless there is evidence of further bleeding.

1. After removing all items from the box, wash the sterile water (diluent) to room temperature (25°C, 77°F).

2. Remove shrink band from product vial.

3. Label the filter needle (from the package) to a sterile syringe. Withdraw the Koate-DVI solution into the syringe through the filter needle (Fig. A). This will establish the right concentration of factor VIII in the syringe.

4. Remove the filter needle from the syringe and replace with an appropriate injection or butterfly needle for administration. Discard filter needles in a puncture proof container, and new equipment should be used.

5. Carefully grip the shaft of the other end of the transfer needles and twist to remove it.

6. Insert the diluent vial and insert the attached needles into the vial at a 45° angle (Fig. C). This will direct the stream of diluent against the wall of the concentrate vial and remove foam. The foam will then be drawn into the concentrate vial (Fig. D). Remove the concentrate vial, directing the stream of fluid against the wall of the concentrate vial.

7. Remove the concentrate bottle and transfer needle (Fig. E). Immediately after adding the diluent, vigorously agitate for 10-15 seconds (Fig. E) then store continually until completely dispensed (Fig. E). Some foaming will occur; but attempt to avoid excessive foaming. The solution should then be visually inspected for particulate matter and discoloration prior to administration.

8. Place the concentrate bottle in a warm place and protect it from light. The concentrate bottle should be kept in a warm place and protected from light.


10. Eyster ME, Bowman HS, Haverstick JN: Adverse reactions to factor VIII infusions. [letter]


A number of factors beyond our control could reduce the efficacy of this product or even result in an adverse effect following its use. These include improper handling and handling of the product after it has been discarded, dosage, method of administration, and biological differences in individual patients. Because of these factors, it is important that the product be stored properly, handled correctly and be used according to the recommendations of the manufacturer. The in vivo percent elevation in factor VIII level can be estimated by multiplying the dose of AHF (H) per kilogram of body weight (IU/kg) by the factor VIII level. Therapy need not be repeated unless there is evidence of further bleeding.

1. After removing all items from the box, wash the sterile water (diluent) to room temperature (25°C, 77°F).

2. Remove shrink band from product vial.

3. Label the filter needle (from the package) to a sterile syringe. Withdraw the Koate-DVI solution into the syringe through the filter needle (Fig. A). This will establish the right concentration of factor VIII in the syringe.

4. Remove the filter needle from the syringe and replace with an appropriate injection or butterfly needle for administration. Discard filter needles in a puncture proof container, and new equipment should be used.

5. Carefully grip the shaft of the other end of the transfer needles and twist to remove it.

6. Insert the diluent vial and insert the attached needles into the vial at a 45° angle (Fig. C). This will direct the stream of diluent against the wall of the concentrate vial and remove foam. The foam will then be drawn into the concentrate vial (Fig. D). Remove the concentrate vial, directing the stream of fluid against the wall of the concentrate vial.

7. Remove the concentrate bottle and transfer needle (Fig. E). Immediately after adding the diluent, vigorously agitate for 10-15 seconds (Fig. E) then store continually until completely dispensed (Fig. E). Some foaming will occur; but attempt to avoid excessive foaming. The solution should then be visually inspected for particulate matter and discoloration prior to administration.

8. Place the concentrate bottle in a warm place and protect it from light. The concentrate bottle should be kept in a warm place and protected from light.


10. Eyster ME, Bowman HS, Haverstick JN: Adverse reactions to factor VIII infusions. [letter]


