Koate-DVI

Consumer Medication Information Leaflet (RiMUP)

Active Ingredient: antihemophilic factor (human) 250 IU / 5 mL

What is in this leaflet

What Koate-DVI is used for

Koate-DVI is used for the treatment and prevention of bleeding, or in order to perform emergency and elective surgery, for patients with haemophilia A (congenital factor VIII deficiency).

Limitation of use

Koate-DVI is not indicated for the treatment of von Willebrand disease.

How Koate-DVI works

Koate-DVI is one of the group of medicines called clotting factors.

Koate-DVI contains human coagulation factor VIII obtained from human plasma.

Koate-DVI temporarily replaces the missing clotting factor in order to control or prevent bleeding episodes.

Before you use Koate-DVI

-When you must not use it

Do not use Koate-DVI if you are allergic to human coagulation factor VIII or to any of the other ingredients of this medicine (see **Further Information**).

If you want more detailed information, then ask your doctor.

- Before you start to use it

Talk to your doctor, pharmacist or nurse before using Koate-DVI.

- Rarely you may have an anaphylactic reaction (a sudden severe allergic reaction) such as rash, tightness of the chest, dizziness, nausea, vomiting, or difficulty breathing. If these symptoms occur, you must stop using the product immediately and contact your doctor.
- Your doctor should perform some tests to make sure that the dosage of Koate-DVI you are receiving is enough to achieve and maintain appropriate coagulation factor VIII levels and thus stop any bleeding.
- If your bleeding is not controlled with Koate-DVI, consult your doctor immediately. You may have developed factor VIII inhibitors. These are antibodies which block the clotting effect of factor VIII. Your doctor will perform some tests to confirm whether the inhibitors are present in your blood.
- If you need large and/or frequent doses of Koate-DVI, and you have blood type A, B, or AB, you may experience a rapid destruction of red blood cells (acute hemolytic anemia) which can lead to bleeding episodes. Your doctor will test you for signs of anemia, and if it is occurring, your doctor will have you stop using Koate-DVI and start appropriate therapy.

Koate-DVI is purified from human plasma obtained from healthy donors. When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded.

However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by: (1) epidemiological controls on the donor population and selection of individual donors by a medical interview; (2) screening of individual donations and plasma pools for viral infection markers; and (3) manufacturing procedures with demonstrated capacity to inactivate/remove pathogens.

Based on the rare occurrence of haemophilia A in women, experience regarding the use of human coagulation factor VIII during pregnancy and breast-feeding is not available.

Koate-DVI has not been studied in children. Koate-DVI has been used extensively in children. Side effects reported by children were no different than those reported by adults.

Koate-DVI has not been studied in patients aged 65 and over to determine whether they respond differently from younger subjects.

Koate-DVI has little or none effect on your ability to drive and use machines.

Ask your doctor or pharmacist for advice before taking any medicine.

See also **Side Effects**.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No interactions of Koate-DVI with other medicines are known.

Do not mix Koate-DVI with any other medicines that you receive by injection.

How to use Koate-DVI

- How much to use

The amount of Koate-DVI you should use depends on many factors, such as your weight, your clinical status and the type and severity of bleeding. Your doctor will calculate the dose, the frequency and the intervals of administration of Koate-DVI in order to reach the necessary level of coagulation factor VIII in your blood.

- When to use it

Talk to your doctor about when you should take Koate-DVI.

- How long to use it

Your doctor will tell you the duration of your treatment with Koate-DVI.

- If you forget to use it

Proceed immediately with the following dose and continue at

regular intervals as directed by your doctor. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

No cases of overdose with Koate-DVI have been reported. However, if you have used more Koate-DVI than required, consult your doctor or pharmacist immediately.

- If you stop using Koate-DVI

Do not stop using Koate-DVI without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

While you are using Koate-DVI

- Things you must do

The product must only be injected directly into a vein (intravenously).

You will be given full training before using Koate-DVI without the hospital supervision. Please refer to all your training materials or contact your local hemophilia center for more information.

Dissolve the product as described at the end of this leaflet (please see **Preparation and Handling** at the end of this leaflet).

Use Koate-DVI within 3 hours after reconstitution.

- Things you must not do

You should not self-administer Koate-DVI alone: always have a responsible adult present.

- Things to be careful of

The administration rate should never be more than 10 mL/min to avoid undesirable side effects.

Side effects

The most common side effects in the clinical trial were nervousness, headache, abdominal pain, nausea, paresthesia (tingling in hands, feet) and blurred vision.

Patients have also reported factor VIII inhibitors; hemolytic anemia; hypersensitivity (allergic reaction) including anaphylaxis, rash, and hives; bleeding from the injection site; and seizure.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reactions Monitoring by calling Tel. 03-78835490, or visiting the website npra.gov.my *[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*

Storage and Disposal of Koate-DVI

- Storage

Keep this medicine out of the sight and reach of children.

- Store Koate-DVI in its original package to protect it from light.
- Store the Koate-DVI package at 2 to 8°C. Do not freeze.
- Koate-DVI may also be stored at room temperature (up to 25°C) for up to 6 months.
- Do not use after the expiration date.
- Use reconstituted Koate-DVI immediately or within 3 hours of reconstitution.

- Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Further Information

- What it looks like

Antihemophilic factor VIII (human) is a sterile, white to pale yellow cake in a glass vial with a stopper, metal ring and plastic cap, and a shrink band.

The diluent vial contains sterile water for injection. The water is clear and colorless.

When reconstituted with the sterile water provided, the Koate-DVI solution is clear to opalescent and colorless to pale yellow.

Each carton is supplied with a single-use vial containing nominally 250 international units (IU) of antihemophilic factor VIII (human), 5 mL sterile water for injection, 1 sterile double-ended transfer needle, 1 sterile filter needle, and 1 sterile administration set.

Each vial and carton of Koate-DVI is labeled with the expiration date.

Koate-DVI also contains naturally occurring von Willebrand factor, a different clotting factor. Koate-DVI contains not less than (NLT) 250 IU naturally occurring von Willebrand factor in the 250 IU presentation. Factor VIII and von Willebrand factor are present in plasma joined together. Both are found bound together in Koate-DVI.

- Ingredients

  - Active ingredient: antihemophilic factor VIII (human)

  - Inactive ingredients: sodium chloride, calcium chloride, L-histidine, human albumin, water

- MAL numbers

250 IU / 5 mL MAL19890637ARZ

Manufacturer

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Preparation and Handling

1. Use aseptic technique (clean and sanitized) and a flat work surface during the reconstitution procedure.

2. Bring the vials of Koate-DVI and the diluent (Sterile Water for Injection) to room temperature before use.

3. Remove the shrink band from the Koate-DVI vial. Do not use Koate-DVI if the shrink band is absent or shows signs of tampering.

4. Remove the plastic cap from the Koate-DVI vial (Fig. A) and clean the top of the stopper with an alcohol swab. Allow the stopper to dry.

5. Repeat this step with the vial of sterile water.

6. Carefully remove the plastic sheath from the short end of the transfer needle and insert the exposed needle into the diluent vial to the hub (Fig. B).

7. Place the Koate-DVI vial upright on a flat surface. Remove the sheath from the other end of the transfer needle.

8. While holding the Koate-DVI vial securely on a flat surface insert the needle into the vial at a 45° angle to minimize foaming (Fig. C). The vacuum will draw the diluent into the concentrate vial. If vacuum is lost, use a sterile syringe and needle to remove the sterile water from the diluent vial and inject it into the Koate-DVI, directing the stream of fluid against the wall of the vial.

9. Remove the diluent vial and transfer needle (Fig. D).

10. Agitate vigorously for 10–15 seconds, (Fig. E1) then swirl continuously until completely dissolved (Fig. E2). Avoid excessive foaming. The reconstituted solution should be clear to opalescent. Do not use if particulate matter and discoloration is observed.

11. Clean the top of the vial of reconstituted Koate-DVI with alcohol swab and let surface dry.

12. Attach the filter needle (from the package) to a sterile syringe. Withdraw the Koate-DVI solution into the syringe through the filter needle (Fig. F).

13. Remove the filter needle from the syringe and discard the filter needle into a puncture proof container. Use Koate-DVI within 3 hours after reconstitution. Do not refrigerate after reconstitution.