APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KOGENATE® FS 250 POWDER FOR INJECTION
KOGENATE® FS 500 POWDER FOR INJECTION
KOGENATE® FS 1000 POWDER FOR INJECTION

DILUENT FOR KOGENATE® FS

Read all of this leaflet carefully before you start taking KOGENATE FS

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **KOGENATE FS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

1. WHAT KOGENATE® FS CONTAINS:

KOGENATE® FS 250 (Formulated with Sucrose)
One vial of lyophilised powder contains 250 IU recombinant antihaemophilic Factor VIII
One prefilled syringe of Diluent for KOGENATE® FS contains 2,5 ml of Sterile Water for Injection

KOGENATE® FS 500 (Formulated with Sucrose)
One vial of lyophilised powder contains 500 IU recombinant antihaemophilic Factor VIII
One prefilled syringe of Diluent for KOGENATE® FS contains 2,5 ml of Sterile Water for Injection

KOGENATE® FS 1000 (Formulated with Sucrose)
One vial of lyophilised powder contains 1000 IU recombinant antihaemophilic Factor VIII
One prefilled syringe of Diluent for KOGENATE® FS contains 2,5 ml of Sterile Water for Injection

Other ingredients are:
Calcium chloride, histidine, glycine, polysorbate 80, sodium chloride, sucrose. The amount of sucrose in each vial is 28 mg. Intravenous administration of sucrose contained in KOGENATE® FS will not affect blood glucose levels.

2. WHAT KOGENATE® FS IS USED FOR?

It helps to prevent and control bleeding in people with haemophilia A. Adults and children of all ages, including newborns, may use KOGENATE® FS.

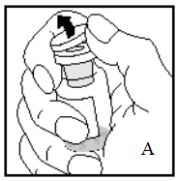
Indicated in patients with Factor VIII inhibitors (neutralizing antibodies) who continue to respond to KOGENATE® FS.

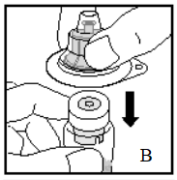
3. BEFORE KOGENATE® FS IS ADMINISTERED:

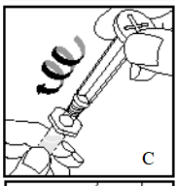
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **KOGENATE® FS** may cause undesirable effects. Please inform your doctor or pharmacist of any other medication you may be taking.

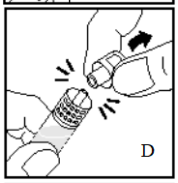
3.1 Do not administer KOGENATE® FS:

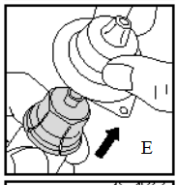
- Known intolerance or allergic reactions to constituents of the preparation.
- Known hypersensitivity to mouse or hamster protein.

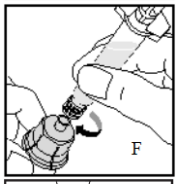


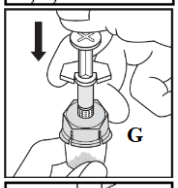


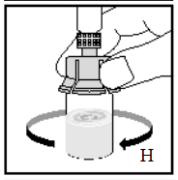


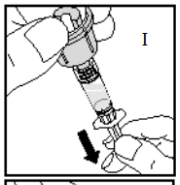


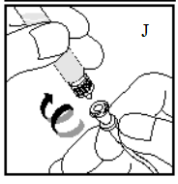












3.2 Using other medicines with KOGENATE® FS:

Interactions with other medicines are not known. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Analgesics such as aspirin, NSAIDs such as ibuprofen or indomethacin impair or prevent blood from clotting, increasing the tendency to bleed and should therefore not be given to haemophiliacs.

3.3 Driving and using machines

No effects on ability to drive or use machines have been observed.

3.4 Pregnancy and breastfeeding

Safety during pregnancy and lactation has not been established.
If you are pregnant or breastfeeding your baby while taking KOGENATE FS, please consult your doctor, pharmacist or other healthcare professional for advice.
If you are taking **KOGENATE FS**, you should not breastfeed your baby.

4. HOW TO USE KOGENATE® FS:

Always use **KOGENATE FS®** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will prescribe a tailored treatment regimen for you that is based on your body weight, the severity of your haemophilia A, and the location and severity of bleeding. You may have periodic blood tests done following infusion of KOGENATE® FS to be sure that the blood level of Factor VIII is high enough to allow satisfactory blood clotting. If your bleeding is not controlled after infusing KOGENATE® FS**,** contact your doctor immediately.

KOGENATE® FS is injected directly into the bloodstream as an intravenous (IV) infusion. You may be infused at a health centre or in your home. Your doctor can teach you the proper technique for self-infusion.

Reconstitution, product administration and handling of the administration set and needles must be done with caution. Percutaneous puncture with a needle contaminated with blood can transmit infectious viruses including HIV (AIDS) and hepatitis. Obtain immediate medical attention if injury occurs.

<u>Medimop Vial Adapter Instructions for use</u>

1. Wash hands thoroughly using soap and warm water.

2. Warm both unopened vial and syringe in your hands to a comfortable temperature (do not exceed 37 °C).

3. Remove protective cap from the vial (A). Aseptically cleanse the rubber stopper with alcohol, being careful not to handle the rubber stopper.

4. Place product vial on a firm, non-skid surface. Peel off the paper cover on the vial adapter plastic housing. Do not remove the adapter from the plastic housing. Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. Do not remove the adapter housing at this step.

5. Carefully open the syringe blister pack by peeling the paper covering back to the midway point. Take out the pre-filled sterile water for injection (SWFI) syringe. Holding the plunger rod by the top plate, take it out of the blister pack. Avoid touching the sides and threads of the plunger rod. Hold the syringe upright, grasp the plunger rod by the top plate and attach the rod by turning it firmly clockwise into the threaded stopper (C).

6. Holding the syringe by the barrel, snap the syringe cap off the tip (D). Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.

7. Now remove and discard the adapter housing (E).

8. Attach the pre-filled syringe to the threaded vial adapter by turning clockwise (F).
9. Inject the diluent by slowly pushing down on the plunger rod (G).
10. Swirl vial gently until all material is dissolved (H). Do not shake vial. Be sure that the powder is completely dissolved. Do not use solutions containing visible particles or that are cloudy.
11. Withdraw solution into the syringe by holding the vial on end above the vial adapter and syringe (I) then draw the plunger rod out slowly and smoothly. Ensure that the entire content of the vial is drawn into the syringe.
12. With the plunger rod in place, remove the syringe from the vial adapter (the latter should remain attached to the vial). Attach the syringe to the administration set provided and inject intravenously (J). NOTE: follow instructions for infusion set provided.
13. If the same patient is to receive more than one vial, reconstitute each vial with the diluent syringe provided then combine solutions in a larger syringe (not provided) and administer as usual.
14. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Rate of administration:

The rate of administration should be adapted to the response of the individual patient, but administration of the entire dose in 5 to 10 minutes or less is well tolerated. Reconstituted product must be used within 3 hours and cannot be stored.

Do not share medicines that are prescribed for you with any other person. It may harm them.
Do not change the dose prescribed by your doctor.

4.1 For how long should you use KOGENATE® FS?
The attending doctor must decide on the length of the treatment.

4.2 What should you do if you have used too little KOGENATE® FS or have forgotten to take a dose?
Do not use more **KOGENATE® FS** next time; simply continue the treatment as prescribed.

4.3 What should you do if you want to interrupt the treatment or stop using KOGENATE® FS before the end of the course?
You should always consult your doctor before deciding to interrupt the course of treatment or stop taking **KOGENATE® FS** altogether.

5. POSSIBLE SIDE EFFECTS:

KOGENATE FS can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Less frequent side effects:
Hypersensitivity reactions including severe sudden allergic reaction (anaphylactic shock, e.g. tightness of the chest/general feeling of being unwell, dizziness and nausea and reduced blood pressure, which may make you feel faint upon standing), fever, dysgeusia.
If you notice any of the following symptoms during injection/infusion:

- chest tightness/general feeling of being unwell, dizziness, mild hypotension (mildly reduced blood pressure, which may make you feel faint upon standing), nausea
- this can constitute an early warning for hypersensitivity and anaphylactic reactions. If allergic or anaphylactic reactions occur, the injection/infusion should be stopped immediately. Please consult your doctor immediately.

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Frequent side effects**:**

- rash/itchy rash, local reactions where you injected the medication (e.g. burning sensation, temporary redness)

Antibodies (Inhibitors)

The formation of neutralising antibodies to factor VIII (inhibitors) is a known complication in the treatment of patients with haemophilia A. Your doctor may wish to carry out tests to monitor inhibitor development.

6. STORING AND DISPOSING OF KOGENATE® FS:

Store in the refrigerator between 2°C to 8°C. Do not freeze. If stored at room temperature (up to 30 ºC), the packed product may be kept for a limited period of 6 months.
Reconstituted product must be used within 3 hours and cannot be stored.
Protect from exposure to light and store the lyophilised powder in the carton prior to use.
Store all medicines out of the reach of children. Do not store in bathrooms.
Return unused or expired medicines to your pharmacist/doctor for safe disposal.
Do not remove from the original packaging until administered.
Do not use after the expiry date stated on the label.

7. PRESENTATION OF KOGENATE® FS:

KOGENATE® FS 250, 500 or 1000:
White to slightly yellow solid lyophilised powder for solution for injection in 10 ml clear tubing glass vial with gray bromobutyl rubber stopper.

HOW KOGENATE FS IS SUPPLIED:
1 vial of lyophilised product (Aluminium cap)
1 diluent prefilled syringe
1 vial adapter
1 administration set

8. IDENTIFICATION OF KOGENATE® FS:

White to slightly yellow solid lyophilised powder (before reconstitution).
Clear liquid after reconstitution with 2,5 ml Water for Injection.

9. REGISTRATION NUMBERS:

KOGENATE® FS 250: A 41/8.1/1086
KOGENATE® FS 500: A 41/8.1/1087
KOGENATE® FS 1000: A 41/8.1/1088

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
27 Wrench Road
Isando, 1609
Registration number: 1968/11192/07

11. DATE OF PUBLICATION:

Date of the registration of the medicine: 10 October 2008
Date of approval of this submission: 02 June 2017

KOGENATE® FS = Registered trade mark of Bayer AG, Germany