

BAYER: KOGENATE FS WITH BIOSET (Recombinant FVIII)

KOGENATE FS, Recombinant Antihemophilic Factor, is indicated for the prevention and control of bleeding episodes in people with hemophilia A (classical hemophilia).

KOGENATE FS is indicated for perioperative management of patients with hemophilia A.

KOGENATE FS is indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no preexisting joint damage.

KOGENATE FS is available in several different potencies; 250, 500, 1000 and 2000. It is packaged with BIO-SET; a self-contained needleless device plus a pre-filled diluent syringe and #25 gauge butterfly needle. KOGENATE FS has a small infusion volume (2.5mL diluent), meaning patients can administer their therapy conveniently and quickly. In addition, while KOGENATE FS should be refrigerated it also has the advantage of being stored for up to three months at room temperature, or up to the expiration date, which ever comes first.

Contraindications:

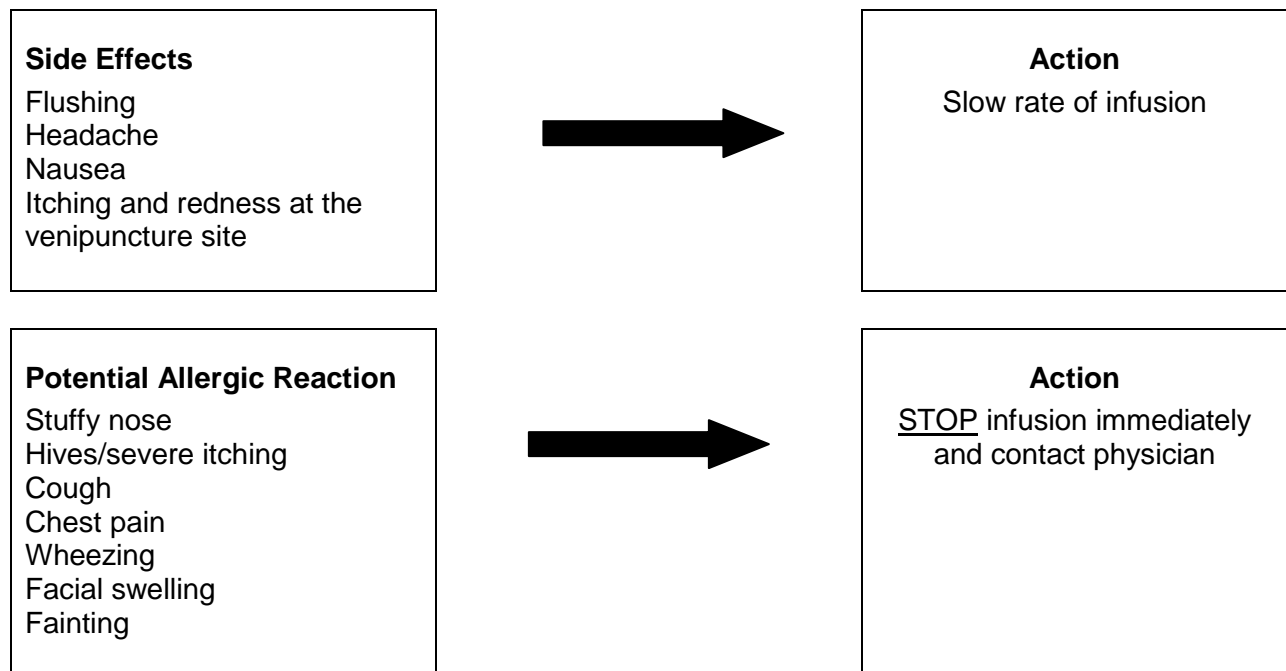
Known hypersensitivity to mouse or hamster proteins.

Known intolerance or allergic reaction to any of the constituents in the formulation of Kogenate FS.

Side Effects:

The most common related adverse reactions observed during the KOGENATE clinical studies, include strange taste in mouth, headache, dizziness and flushing.

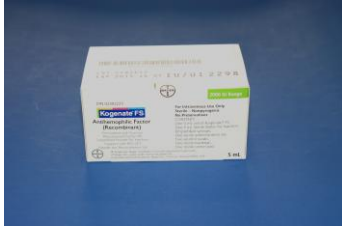
Management of Adverse Effects:



LINK to WEBSITE for PRESCRIBING INFORMATION

Product insert available at http://berlex.bayerhealthcare.com/html/products/pi/Kogenate_BIO-SET_PI.pdf

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STEP 1

Bring Kogenate FS with BIO-SET to room temperature before using. Choose a clean, dry, well-lit work area and lay out the following supplies contained within the box:

- BIO-SET containing recombinant factor FVIII powder
- Blister pack containing glass syringe with diluent and plunger
- 25 gauge butterfly with inline filter



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 cap from the BIO-SET containing FVIII powder by twisting it side to side and removing it.



STEP 4

Carefully open the blister pack by peeling the paper covering back to the midway point. Take out the diluent prefilled syringe and remove the tip cap by pushing to one side until it comes off (the grey rubber pieces come off).



STEP 5

Connect the syringe by screwing it on to the top of the BIO-SET.

**** IMPORTANT STEP, DO NOT MISS****



STEP 6

Hold the BIO-SET firmly on a rigid, non-skid surface with one hand. With the other hand, press firmly down on the fingerplate near the syringe tip until it meets the top edge of the BIO-SET. A bubble will surface and a small quantity of diluent will go in to the BIO-SET vial. The system is now **ACTIVATED**.



STEP 7

Grasp the plunger rod at the top and remove from the blister pack. Immediately screw the plunger rod into the rubber stopper.



STEP 8

Slowly press the plunger rod all the way into the syringe to inject the diluent into the powder.



STEP 9

Mix the factor in the vial by gently and slowly swirling it around until the entire factor is liquid. Do not shake the vial.

STOP HERE:

- a) Go to Step 12 if prescribed dose requires more than one vial.
- b) Go to Step 14 if using a Port-a-Cath® or established IV
- c) Go to Step 20 if not using the butterfly (with inline filter) provided in the box containing Kogenate FS



STEP 10

Turn the vial and syringe upside down and pull the plunger until all the factor is in the syringe. Tip the vial to the side to help the factor flow in to the syringe.



STEP 11

Unscrew the syringe from the empty vial by turning it to the left or counterclockwise. **DO NOT PULL OFF THE SYRINGE BEFORE UNSCREWING IT.** Connect the syringe to the butterfly. Remove air in tubing by gently pushing on the plunger.

The entire dose of Kogenate FS can usually be infused within 1 to 15 minutes through IV direct push (through peripheral vein or Port-a-Cath®). The rate of administration however, should be adapted to the response of each individual patient. Dispose of butterfly needle or winged infusion set in sharps container.



MULTIVIAL DOSE

STEP 12

Follow steps 1 – 9 of the Kogenate FS with BIO-SET instructions to prepare the prescribed dose to the nearest vial.

STEP 13

Remove the syringe from the first vial only. Attach 10cc luer lock syringe. Turn the vial and syringe upside down and pull the plunger until all the factor is in the syringe.

Unscrew the syringe from the second vial and attach the 10 cc syringe containing the factor. Pull the plunger until all the factor is in the syringe. Repeat until all the factor from the vials is in the larger syringe. Go to Step 11.

USING A PORT-A-CATH® OR ESTABLISHED IV



STEP 14

Follow steps 1 – 9 of the Kogenate FS with BIO-SET instructions to prepare the prescribed dose to the nearest vial. Additional supplies include a 10 cc luer lock syringe, an Injection Filter and blunt cannula.

IMPORTANT

When using a Port-a-Cath®, always use a syringe equal to or greater than 10cc.



STEP 15

Remove the empty syringe from the BIO-SET vial. Partially open the filter pouch by peeling back the paper with the ↑↑↑. Attach the Injection Filter to the BIO-SET vial if the narrow end of the injection filter is exposed. During the connection process the filter should be held from the outside of the pouch without touching the filter.



STEP 16

If the wide end of the Injection Filter is exposed first attach a sterile 10 cc luer lock syringe to the Injection Filter. Attach the BIO-SET vial and syringe with the Injection Filter between.



STEP 17

Turn the vial and syringe upside down and pull the plunger until all the factor is in the syringe. Tip the vial to the side to help the factor flow in to the syringe.



STEP 18

Remove syringe containing factor from Injection Filter attached to BIO-SET. Attach blunt cannula to 10cc syringe containing factor.



STEP 19

Mark syringe with tape or label for Port-a-Cath® administration.