PART III: CONSUMER INFORMATION

KOGENATE® FS

Antihemophilic Factor (Recombinant)

Formulated with Sucrose

Supplied with BIO-SET

Needle-less Reconstitution Set

This leaflet is Part 3 of a three-part "Product Monograph" published when *KOGENATE FS* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about *KOGENATE FS*. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

KOGENATE FS (Antihemophilic Factor [Recombinant]) is used for the treatment of hemophilia A. Patients who have hemophilia A do not have enough clotting Factor VIII, which helps control bleeding. KOGENATE FS can be used to prevent bleeding before it happens, or it can be used to stop a bleeding episode that has already begun in patients who have hemophilia A.

When used as a regular prophylactic treatment, KOGENATE FS is indicated to prevent the occurrence of spontaneous hemorrhagic episodes and to prevent joint damage in children. KOGENATE FS is also indicated to prevent and control bleeding in adults with hemophilia A when used regularly.

What it does:

KOGENATE FS is clotting Factor VIII that has been developed in the laboratory. It is very similar to the Factor VIII that occurs naturally in human blood. In patients with hemophilia A, who do not have enough natural Factor VIII in their blood, KOGENATE FS gives them additional Factor VIII to help prevent and/or control bleeding. KOGENATE FS is given directly into the blood through an injection in a vein.

When it should not be used:

KOGENATE FS does not contain von Willebrand Factor and therefore, is not indicated for the treatment of von Willebrand disease.

What the medicinal ingredient is:

Antihemophilic Factor (Recombinant)

What the nonmedicinal ingredients are:

- Sucrose
- Glycine
- Histidine
- Calcium chloride
- Sodium chloride
- Polysorbate 80

KOGENATE FS does not contain any preservatives.

What dosage forms it comes in:

KOGENATE FS is a dried product powder available in vials containing 250 IU*, 500 IU, 1000 IU, (with 2.5 mL Sterile Water for Injection), 2000 IU, and 3000 IU (with 5.0 mL Sterile Water for Injection) supplied with BIO-SET needle-less reconstitution set. A prefilled syringe containing Sterile Water for Injection for reconstitution and a sterile administration set are also provided. After reconstitution, KOGENATE FS is given by direct injection into a vein, usually over 5 to 10 minutes. You may also receive treatment presurgery by an initial bolus (all at once) injection followed immediately by continuous infusion.

* IU = International Units

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Some people can develop *inhibitors* to treatment with Factor VIII.

Inhibitors to treatment with Factor VIII are antibodies that can reduce the effectiveness of treatment. Anyone can develop inhibitors, but they are especially common in young children with severe hemophilia during their first years of treatment and any patient who has had little previous treatment with Factor VIII. Your hemophilia healthcare team will monitor you carefully for the development of inhibitors.

Be careful when handling the administration set and needle, to minimize the possibility of accidental needlestick injuries. Contact your healthcare team immediately if you accidentally injure yourself.

Rarely, some people have allergic reactions to Factor VIII. If you develop low blood pressure, a rash, hives, wheezing, or tightness in your chest, seek immediate emergency treatment.

BEFORE you use KOGENATE FS talk to your doctor or pharmacist if

- you are allergic to mouse or hamster protein, or any of the ingredients in KOGENATE FS.
- you have had inhibitor development in the past.
- you have been told you have heart disease or are at risk for heart disease.
- you are pregnant, are trying to become pregnant or are a nursing mother.

INTERACTIONS WITH THIS MEDICATION

None known.

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

PROPER USE OF THIS MEDICATION

Usual dose

Your doctor will calculate the best dosage for you, based on your weight, blood tests of your Factor VIII level, and whether KOGENATE FS is being used to prevent or stop a bleeding episode. You and your healthcare team will work together to find out what dosage and schedule works best for you.

General guidelines for dosage:

- A minor bleeding episode will be treated with 10-20 IU for every kilogram of body weight.
- A moderate/major bleeding episode will be treated with 15-30 IU for every kilogram of body weight.
- A major/very serious bleeding episode will be treated with 40-50 IU for every kilogram of body weight.
- Surgical procedures may require 50 IU for every kilogram of body weight before the operation. You may also receive treatment presurgery by an initial bolus (all at once) injection followed immediately by continuous infusion.
- Patients who have inhibitors may require higher dosages.
- The regular prophylaxis schedule for children is 25 IU/kg of body weight every other day.
- The regular prophylaxis schedule for adults is 25 IU/kg of body weight three times per week.

Overdose

No symptoms of overdose have been reported.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

In patients who have had previous treatment with Factor VIII, some side effects included reactions at the injection site, rash and itchy skin.

In patients who had no previous treatment with Factor VIII, some side effects included formation of inhibitors to Factor VIII, reactions at the injection site, rash, and itchy skin.

You may find that more KOGENATE FS is required than estimated to stop the bleeding (lack of effect).

If you are concerned about any possible side effects, talk to your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect	Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical treatment
	Only if severe	In all cases	
Common			
Lack of Effect		✓	
Uncommon			
Allergic Reaction: low blood pressure, rash, hives, wheezing, or tightness in your chest			✓

This is not a complete list of side effects. For any unexpected effects while taking *KOGENATE FS*, contact your doctor or pharmacist.

HOW TO STORE IT

Keep KOGENATE FS Supplied with BIO-SET Needle-less Reconstitution Set in the refrigerator (2°C-8°C). You may store the powder at room temperature up to 25°C for 12 months. If the KOGENATE FS is stored outside the refrigerator, please add the date removed from refrigeration and note a new expiry date on the carton and vial. The next expiry date is 12 months from the date product is removed from the refrigerator, or the previously stamped expiry date, whichever is shorter. Once KOGENATE FS has been removed from refrigeration, it cannot be returned to the refrigerator. Store away from extreme light and do not use after the expiration date on the bottle. Do not freeze. Store the powder in the carton.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online:	www.healthcanada.gc.ca/medeffect
Call toll-free at:	1-866-234-2345
Complete a Canada Vigilance Reporting Form and:	
Fax toll-free to:	1-866-678-6789, or
Mail to:	Canada Vigilance Program Health Canada Postal Locator 0701D Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at:

www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be obtained at www.bayer.ca or by contacting the manufacturer at the above-mentioned phone number and email address.

This leaflet was prepared by:

Bayer Inc.
2920 Matheson Boulevard East
Mississauga, Ontario
L4W 5R6

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