KOGENATE® FS

(with BIO-SET)

octocog alfa (bhk) (recombinant Factor VIII)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about KOGENATE FS

This leaflet does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking KOGENATE FS against the benefits they expect it will have for you.

KOGENATE FS should only be used under medical supervision.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT KOGENATE FS IS USED FOR

KOGENATE FS will both help to prevent and treat bleeding, occurring either spontaneously or due to injury, and bleeding during emergency and surgical procedures, by temporarily providing additional Factor VIII.

BEFORE YOU USE KOGENATE FS

When you must not use it

Do not use KOGENATE FS if you have an allergy to:

- any medicine containing octocog alfa (bhk) (recombinant Factor VIII)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

As KOGENATE FS contains trace amounts of mouse and hamster proteins, a possibility exists that patients treated with this product may develop hypersensitivity to these non-human proteins. If you experience any of these symptoms, you should stop the injection at once and seek medical attention immediately.

Do not use KOGENATE FS after the expiry date (EXP) printed on the pack.
The expiry date is printed on the carton and vial after "EXP" (e.g. 3 NOV 18 refers to 3 November 2018). If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.
If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Use in children

KOGENATE FS has been shown to be effective in children.

Before you start to use it

Tell your doctor if you are pregnant or breastfeeding .
Experience regarding the use of KOGENATE FS during pregnancy and during breastfeeding is not available because of the rare occurrence of haemophilia in women. However, if you are receiving KOGENATE FS treatment and you are pregnant or suspect you are pregnant, you must contact your doctor for advice.

Breastfeeding is not recommended if you are being treated with KOGENATE FS.

Tell your doctor if you have previously had an allergic or hypersensitivity reaction to other Factor VIII products.
Serious allergic and hypersensitivity reactions with Factor VIII have been reported, particularly in very young patients who had previously reacted to other Factor VIII products.

Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using KOGENATE FS.

Taking other medicines

Whilst being treated with KOGENATE FS, you must seek your doctor's advice before taking any other medication, whether provided on a prescription or bought from a pharmacy, supermarket or health food shop.

You should avoid taking some analgesic/anti-inflammatory painkillers such as aspirin, phenylbutazone, and indomethacin that increase the risk of bleeding.

HOW TO USE KOGENATE FS

KOGENATE FS is a SINGLE-USE ONLY product

How much to use

The amount of KOGENATE FS you need and the frequency with which it should be used will depend on the clinical effect.

Your doctor will determine the correct dosages based on the severity of your condition, depending on your body weight, the extent of bleeding and whether KOGENATE FS is given to prevent or treat bleeding. Tests to measure the circulating levels of Factor VIII in your blood will be performed at intervals and are important to monitor the effectiveness of the treatment.

How to use it

For infusion, the product must be prepared under aseptic conditions. If any component of the package is opened or damaged, do not use this component.

KOGENATE FS should be inspected visually for particulate matter and discolouration prior to administration. Do not use KOGENATE FS if you notice any particulates or turbidity in the solution.

KOGENATE FS should be reconstituted and administered with the components provided with each package.

The reconstituted product must be filtered prior to administration to remove potential particulate matter in the solution. Filtering can be achieved by following the reconstitution and/or administration steps as described below.

It is important to use the administration set provided with the product for administration as it incorporates an in-line filter. In situations where the administration set provided cannot be used (e.g. when infusing into a peripheral or central line), a separate filter compatible with KOGENATE FS should be used.

The administration set provided with the product must not be used for drawing blood because it contains an in-line filter. When blood must be withdrawn prior to infusion, use an administration set without a filter, then infuse KOGENATE FS through an injection filter.

Wash your hands thoroughly before preparing to administer KOGENATE FS.

If you are not administering to yourself, wear gloves to avoid contact with blood.

Reconstitute KOGENATE FS powder with the diluent provided before use. Prepare KOGENATE FS when you are ready to use it. KOGENATE FS should be administered by intravenous (into a vein) injection as soon as possible after reconstitution (no later than 3 hours after reconstitution) .

If the solution is not injected immediately after reconstitution, leave the syringe attached to the vial containing the solution to maintain sterility of the product. Refrigeration of reconstituted KOGENATE FS solution should be avoided. Any unused solution **must** be discarded.

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

The complete set of instructions on how you should reconstitute and administer KOGENATE FS is provided at the end of this document.

If you have any doubts about how to reconstitute or administer KOGENATE FS, please consult your doctor, pharmacist or Haemophilia Treatment Centre.

When to use it

You can inject KOGENATE FS at any time of day, before or after meals.

If you use too much (overdose)

Telephone your doctor or the Poisons Information Centre immediately (telephone Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764 766) if you think that you or anyone else may have used too much KOGENATE FS.

SIDE EFFECTS

Tell your doctor if you notice any of the following and they worry you:

- dizziness
- a mild increase or decrease in your blood pressure
- nausea

- a running nose

Tell your doctor immediately if you notice any of the following:

- a local reaction around the site of the injection (e.g. a burning sensation, transient reddening of the skin)
- rash, itching on the skin

If the following happens, stop using KOGENATE FS immediately, and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- skin rashes, breathlessness, wheezing, tightness of the chest, decreased blood pressure (feeling faint)

These are signs of a serious allergic and hypersensitivity reaction. You may need immediate emergency treatment with resuscitative measures such as the administration of adrenaline and oxygen. These reactions are very rare.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Inhibitors
Treatment with Factor VIII products such as KOGENATE FS may sometimes lead to the formation of antibodies (inhibitors) which neutralise Factor VIII and reduce the effectiveness of the treatment. Your doctor will monitor you for development of these inhibitors and if they suspect that an inhibitor is present, the level of inhibitor will be measured using the appropriate laboratory tests. In some patients, inhibitors can be successfully overcome with larger doses of Factor VIII, but for some patients it may be necessary to switch to a different treatment.

AFTER USING KOGENATE FS

Storage

Keep KOGENATE FS together with the prefilled diluent syringe in the refrigerator.

DO NOT FREEZE.

For use at home, the product may be stored at 30°C (normal room temperature) for up to 6 months. Write the date at which the 6-month period ends on the vial and carton label. At the end of this period, the product must be discarded.

Do not use the product after this date.

Do not return the product to the refrigerator after it has been stored at 30°C.

Protect KOGENATE FS from exposure to light. Keep the KOGENATE FS vial in its carton until just prior to use.

Disposal

If not used, the vial and carton should be returned to the Haemophilia Treatment Centre just prior to expiry.

KOGENATE FS should be used once only. After injecting, you should discard the syringe even if you have not injected all of its contents. Syringes should be discarded in an appropriate disposal unit. Any unused solution must be discarded.

If your doctor tells you to stop using KOGENATE FS or if it has passed its expiry date, ask your doctor or pharmacist what to do with any product or syringes that are left over.

PRODUCT DESCRIPTION

What it looks like

KOGENATE FS is a white to slightly yellow powder before reconstitution and a clear liquid after reconstitution with water for injection. It comes in a clear glass vial with a rubber stopper.

KOGENATE FS contains the active ingredient octocog alfa (bhk) (recombinant Factor VIII) as a sterile, highly purified, freeze-dried powder.

KOGENATE FS is produced from genetically engineered bhk (baby hamster kidney) cells into which the genetic code for human Factor VIII has been inserted.

KOGENATE FS does not contain von Willebrand factor and therefore **is not suitable for patients requiring treatment of von Willebrand's disease**. Otherwise, KOGENATE FS has the same biological effects as Factor VIII derived from human plasma.

KOGENATE FS comes in the following dose strengths:

- 250 IU
- 500 IU
- 1000 IU
- 2000 IU
- 3000 IU

Ingredients

Each single-use vial of KOGENATE FS powder for injection contains:

Active ingredient:
octocog alfa (bhk) (recombinant Factor VIII)

Inactive ingredients:

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

Trace amounts of mouse and hamster protein are also present.

Each single-use prefilled diluent syringe contains sterile water for reconstitution and injection.

KOGENATE FS contains no preservatives.

Your pack contains:

- 1 vial of KOGENATE FS (powder for injection) 250 IU, 500 IU, 1000 IU, 2000 IU, or 3000 IU with BIO-SET
- 1 prefilled diluent syringe with sterile water for reconstitution and injection: 2.5 mL for 250 IU, 500 IU, 1000 IU and 5 mL for 2000 IU, 3000 IU
- 1 sterile administration set
- 1 plunger rod
- 2 alcohol swabs
- 1 cotton pad
- 1 bandage

Supplier

Made in USA for:
Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble, NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest
North Shore, Auckland 0627

Australian Registration Numbers
KOGENATE FS 250 IU - AUST R 77689
KOGENATE FS 500 IU - AUST R 77688KOGENATE FS 1000 IU - AUST R 77690
KOGENATE FS 2000 IU - AUST R 153830
KOGENATE FS 3000 IU - AUST R 173675

Not all presentations are marketed.

Date of Preparation
May 2013

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

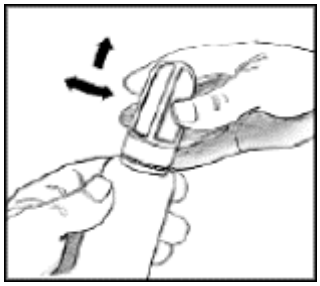
See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

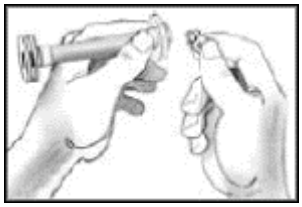
HOW TO USE IT

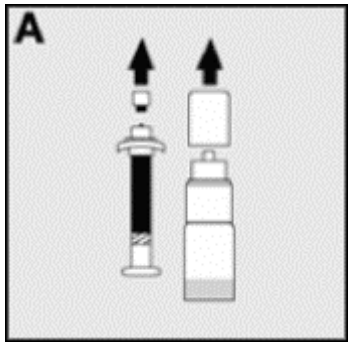
Reconstitution

Wash your hands thoroughly before performing the following procedures. Prepare the solution on a clean, dry, non-slip surface.

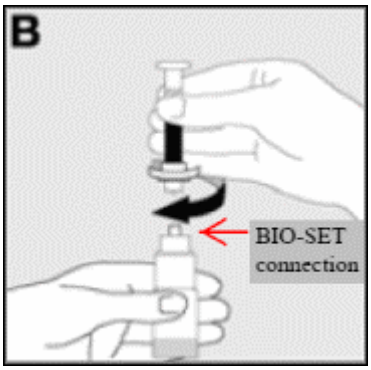
1. Warm the unopened powder vial and the diluent syringe in your hands to approximately body temperature (do not exceed 37 °C). Wipe any observable moisture from the vial.
2. Remove the cap from the powder vial by gently rocking it from side to side several times, whilst at the same time pulling upwards. Remove the stopper attached to the white cap from the diluent syringe (Figure A).



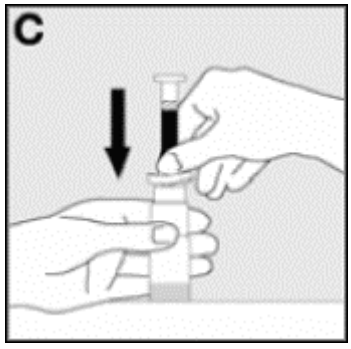


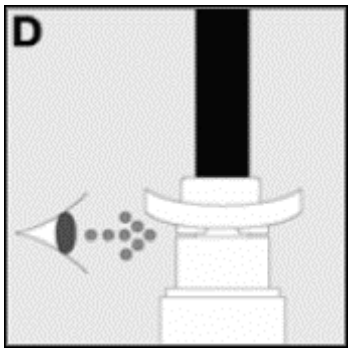


3. Connect the diluent syringe to the powder vial by gently screwing the syringe on to the BIO-SET connection of the powder vial (Figure B).

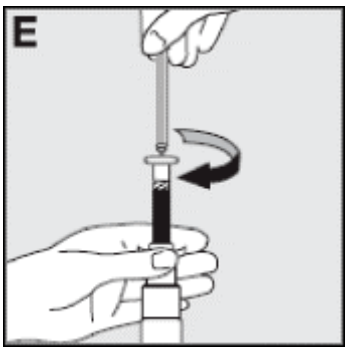


4. Place the vial on a clean, dry, non-slip surface and hold it firmly with one hand. With the other hand, strongly press down on the fingerplate near the syringe tip using your thumb and index finger (Figure C) until the finger plate meets the top edge of the BIO-SET. A "click" will be heard. This indicates that the system is activated (Figure D).

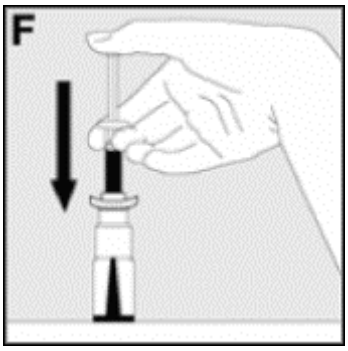




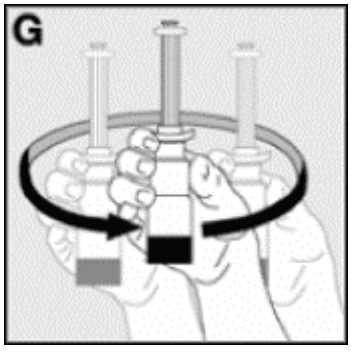
5. Insert the plunger rod into the syringe barrel and screw it into the rubber stopper (Figure E).



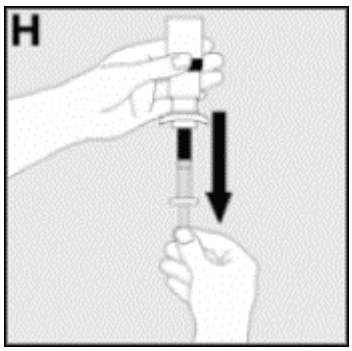
6. Inject the diluent into the powder by slowly pushing down on the syringe plunger rod (Figure F).



7. Dissolve the powder by gently swirling the vial (Figure G). Do not shake the vial. Ensure that the powder is completely dissolved without excessive foam before use. Do not use solutions that contain visible particles or that are cloudy or discoloured.



8. Invert vial/syringe and transfer the solution into the syringe by drawing the plunger rod out slowly and smoothly (Figure H). Ensure that the entire contents of the reconstituted KOGENATE FS vial are drawn into the syringe.



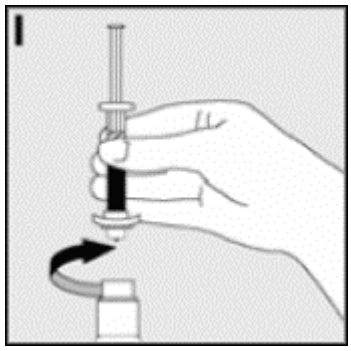
9. If you need more than one dose, reconstitute the desired amount of product repeating steps 1-8 above. Use a new syringe.

Administration

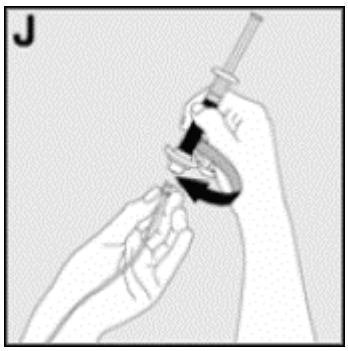
If you are not administering to yourself, wear gloves to avoid contact with blood.

It is important to use the administration set provided with the product for administration as it incorporates an in-line filter. In situations where the administration set provided cannot be used (e.g. when infusing into a peripheral or central line), a separate filter compatible with KOGENATE FS should be used.

1. Apply a tourniquet. Determine the point of injection. Prepare the site of injection aseptically by cleaning the skin with an alcohol swab and letting it dry, or as advised by your doctor. Firmly grasp one or both wings of the administration set to puncture the vein and secure the administration set. NOTE: Follow instructions for administration set provided.
2. Remove tourniquet.
3. Unscrew the filled syringe to disconnect from the empty vial (Figure I).



4. Attach the filled syringe to the administration set by screwing it clockwise and ensure that no blood enters the syringe (Figure J).



5. Inject the solution slowly over several minutes (from 1-2 mL per minute), keeping an eye on the position of the needle. The rate of administration should be adapted to the response of the individual patient, but administration of the entire dose in 5-10 minutes or less is well tolerated.
6. If a further dose is required, remove the empty syringe by turning it anti-clockwise. Connect the newly prepared syringe. Follow steps 4-5 above.
7. If no further dose is required, remove the administration set and syringe. Hold a cotton pad firmly over the injection site on the outstretched arm for approximately 2 minutes. Finally, apply a small pressure dressing to the wound.

Place needles in a sharps container after single-use. Discard all equipment, including any reconstituted KOGENATE FS product, in accordance with biohazard procedures.