

Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Human Coagulation Factor VIII (rDNA) I.P.

Moroctocog alfa (AF-CC) (r-DNA origin)

250 IU, 500 IU, 1000 IU, 2000 IU Lyophilized

Powder for Reconstitution

xynthophiliaTM

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is and what it is used for
2. What you need to know before you take xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)
3. How to take xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)
4. Possible side effects
5. How to store xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)
6. Contents of the pack and other information

1. What xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is and what it is used for

xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) contains the active substance moroctocog alfa, human coagulation factor VIII.

xynthophiliaTM Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), Antihemophilic Factor (Recombinant) [BDDrFVIII], indicated for the control

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and prevention of haemorrhagic episodes and for routine and surgical prophylaxis in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia).

2. What you need to know before you take xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) Do not take xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)

- If you are allergic to moroctocog alfa or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to hamster proteins.

If you are unsure about this, ask your doctor.

Warnings and precautions

Talk to your doctor before using xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)

- If you experience allergic reactions. Some of the signs of allergic reactions are difficulty in breathing, shortness of breath, swelling, hives, itching, tightness of the chest, wheezing, and low blood pressure.
- The formation of inhibitors (antibodies that neutralizes xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)) is a known complication that can occur during treatment with all factor VIII medicines. These inhibitors, especially at high levels, stop the treatment from working properly and you will be monitored carefully for the development of these inhibitors.
- If your bleeding does not stop as expected and contact your doctor or seek immediate emergency care.
- If you have cardiovascular risk factors, substitution therapy with factor VIII may increase the cardiovascular risk.
- If a central venous access device (CVAD) is required, the risk of CVAD-related complications including local infections, bacteraemia, and catheter site thrombosis should be considered.

Other medicines and xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) has no influence on the ability to drive or use machines.

3. How to take xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Treatment with xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) should be started by a doctor who is experienced in the care of patients with haemophilia A. Your doctor will decide the dose of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) you will receive. This dose and duration will depend upon your individual needs for replacement factor VIII therapy. xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is given by injection into a vein lasting several minutes.

During your treatment, your doctor may decide to change the dose of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) you receive.

It is recommended that every time you use xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), you record the name on the carton and batch number of the product. You can use one of the peel-off labels found on the pre-filled syringe to document the batch number in your diary or for reporting any side effects.

Reconstitution and administration

The procedures below are provided as guidelines for the reconstitution and administration of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) provided in a pre-filled syringe. Patients should follow the specific reconstitution and administration procedures provided by their doctors.

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is administered by intravenous (IV) infusion after reconstitution of the lyophilized powder with the supplied pre-filled diluent (0.9% Sodium Chloride solution) syringe. Use only the materials provided in the Kit.

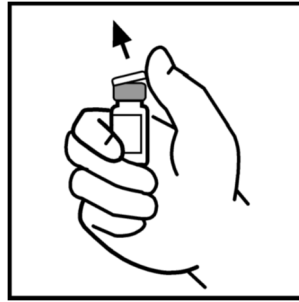
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Preparation

1. Always wash your hands before performing the following procedures.
2. Aseptic technique (meaning clean and germ-free) should be used during the reconstitution procedure.
3. All components used in the reconstitution and administration of this product should be used as soon as possible after opening their sterile containers, to minimise unnecessary exposure to the air.

Reconstitution

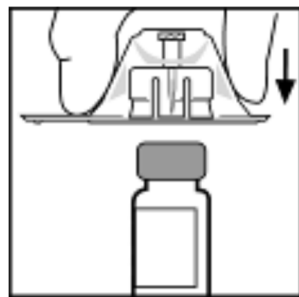
1. Allow the vial of freeze-dried xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) powder and the pre-filled diluent syringe to reach room temperature.
2. Remove the plastic flip-top cap from the xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) vial to expose the central portions of the rubber stopper.



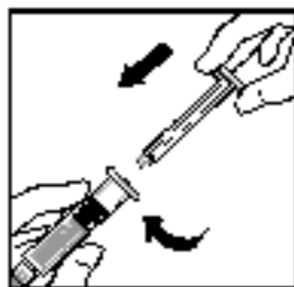
3. Wipe the top of the vial with alcohol swab or use another antiseptic solution, and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface. If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol swab for each vial.

4. Peel back the cover from the clear plastic vial adapter package. Do not remove the adapter from the package.

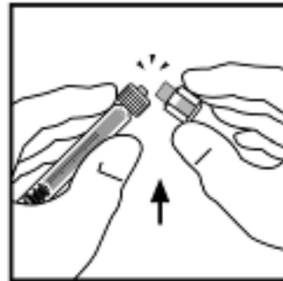
5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.



6. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe by pushing and turning firmly.



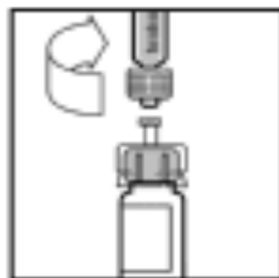
7. Break off the tamper-resistant, plastic-tip cap from the diluent syringe by snapping the perforation of the cap. This is done by bending the cap up and down until the perforation is broken. Do not touch the inside of the cap or the syringe tip. The diluent syringe may need to be recapped (if the dissolved xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is not used immediately), so place the cap on its top on a clean surface in a spot where it would be least likely to become contaminated.



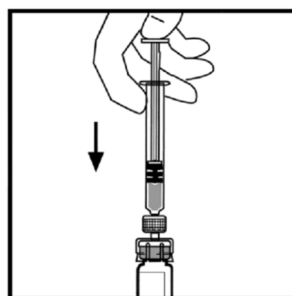
8. Lift the package away from the adapter and discard the package.



9. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



10. Slowly depress the plunger rod to inject all the diluent into the xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) vial.

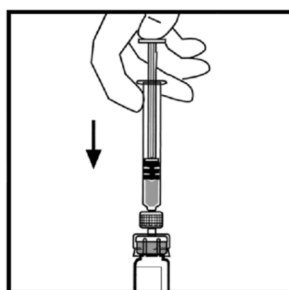


11. With the syringe still connected to the adapter, gently swirl the contents of the vial until the powder is dissolved.

Note: The final solution should be inspected visually for particulate matter before administration. The solution should be clear to slightly pearly and colorless. If it is not, the solution should be discarded and a new kit should be used.

12. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw the solution into the syringe.

Note: If you prepared more than one vial of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), remove the diluent syringe from the vial adapter, leaving the vial adapter attached to the vial. Quickly attach a separate large luer lock syringe and draw back the dissolved contents as instructed above. Repeat this procedure with each vial in turn. Do not detach the diluent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter.



13. Detach the syringe from the vial adapter by gently pulling and turning the syringe counter clockwise. Discard the vial with the adapter attached.

Note: If the solution is not to be used immediately, the syringe cap should be carefully replaced. Do not touch the syringe tip or the inside of the cap.

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) should be infused within 3 hours after dissolving. The dissolved solution may be stored at room temperature prior to infusion.

Administration (Intravenous Infusion)

Your doctor or healthcare professional should infuse Xynthophilia (Moroctocog alfa) following the instructions in this Package Leaflet

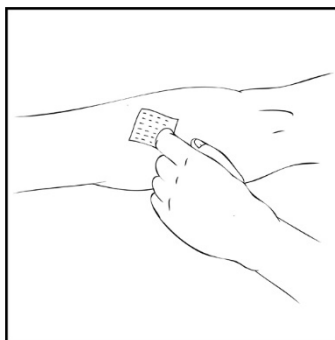
xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is administered by intravenous (IV) infusion after reconstitution of the powder with the solvent (0.9% sodium chloride). Once reconstituted, xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) should be inspected for particulate matter and discolouration prior to administration.

Always wash your hands before doing the following procedures. Germ-free methods should be used during injection.

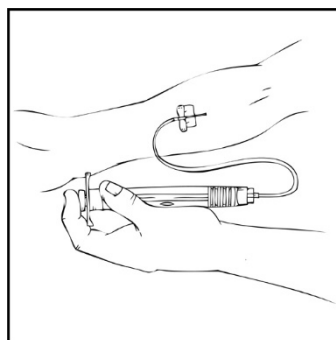
xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) should be administered using the pre-filled diluent syringe provided or a single sterile disposable plastic luer-lock syringe. In addition, the solution should be withdrawn from the vial using the vial adapter.

1. Attach the syringe to the luer end of the infusion set tubing and perform venipuncture as instructed by your hemophilia doctor or nurse.

2. Apply a tourniquet and prepare the injection site by wiping the skin well with an alcohol swab. If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol swab for each vial. Do not use the injection needle to withdraw the medicine from vial.



3. Insert the needle on the infusion set tubing into the vein, and remove the tourniquet. Infuse the reconstituted xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) product over several minutes. Your comfort level should determine the rate of infusion.



4. After injecting xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), remove the infusion set and discard. The amount of drug product left in the infusion set will not affect your treatment. Dispose of all unused solution, the empty vial(s), and the used needles and syringes in an appropriate sharps container used for throwing away waste that might hurt others if not handled properly.

You should record the lot number of the product every time you use xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin). The lot number can be found on the vial label. The peel-off label on the vial may be used to record the lot number.

The reconstituted xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) solution does not contain a preservative and should be used within 3 hours of reconstitution.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)

- inhibitor development for patients who have never been previously treated with factor VIII products

Common side effects (may affect up to 1 in 10 people)

- inhibitor development for patients who have been previously treated with factor VIII products (less than 1 in 100 patients)

Rare:

- Increases in antibodies for certain proteins in labs. Ask your doctor to know more.
- Headache
- Cough
- Joint pain
- Fever, chills, catheter site reaction
- Dizziness
- Bleeding and hematoma
- Rash
- Vomiting, nausea, diarrhoea and abdominal pain

Very Rare:

- Severe allergic reaction
- Neuropathy, sleepiness, altered taste
- Chest pain, rapid heart beat, palpitations
- Low blood pressure, pain and redness of veins associated with a blood clot, flushing
- Shortness of breath
- Excessive sweating
- Weakness, injection site reactions including pain
- Slight increase in heart enzymes
- Increased liver enzymes, increased bilirubin
- Hives, rash, itching
- Muscular pain

5. How to store xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin)

Store under refrigeration at a temperature of 2°C to 8°C.

For your convenience, the medicine can be removed from such storage for one single period of maximum 3 months at room temperature (up to 25°C). After room temperature storage, the product can be returned to refrigerated storage until the expiration date. The diluent syringe should be stored at 2°C to 25°C and should not be used subsequent to expiration.

Do not store xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) vial at room temperature and return it to refrigerated storage more than once. Do not use xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) vial after the expiry date on the label.

Record on the outer carton the date xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) pre-filled syringe is removed from the refrigerator and set at room temperature (up to 25°C).

Keep the pre-filled syringe in the outer carton in order to protect from light.

Use the reconstituted solution within 3 hours of reconstitution or removal of the grey tip cap.

6. Contents of the pack and other information

What xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) contains

Each single use vial contains either 250 IU, 500 IU, 1000 IU, 2000 IU of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin).

List of Excipients:

The excipients are polysorbate 80 (0.4 mg/vial), sucrose (12 mg/vial), L-Histidine (6 mg/vial), calcium chloride dihydrate (1 mg/vial), sodium chloride (36 mg/vial) [after reconstitution with diluent].

What xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) looks like and contents of the pack

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) is provided as a lyophilized powder for reconstitution in a vial and one prefilled diluent syringe.

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), Antihemophilic Factor (Recombinant) freeze-dried is supplied in kits that include single-use vials that contain nominally 250 IU, 500 IU, 1000 IU, 2000 IU per vial. Actual factor VIII activity in IU is stated on the label of each Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), Antihemophilic Factor (Recombinant) vial.

The content of the pack are:

Each xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) Antihemophilic Factor (Recombinant) kit contains: 1 pre-filled diluent syringe containing 4 mL of 0.9% Sodium Chloride solution for injection with plunger rod for assembly, 1 vial adapter, 1 sterile infusion set, 2 alcohol swabs, 1 bandage, 1 gauze, and 1 package insert.

xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin), Antihemophilic Factor (Recombinant) can also be supplied in a pack presentation kit containing: 3 vials of xynthophilia™ Human Coagulation Factor VIII (rDNA) I.P. (Moroctocog alfa) (AF-CC) (r-DNA origin) lyophilized powder for reconstitution, 3 labeled pre-filled diluent syringes containing each 4 mL of 0.9% Sodium Chloride solution for injection, 3 vial adapters and 1 package insert.

Not all strengths/pack Presentation may be marketed.

Imported and Marketed by:

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