**Package leaflet: information for the user**

# ELOCTA 250 IU powder and solvent for solution for injection
# ELOCTA 500 IU powder and solvent for solution for injection
# ELOCTA 750 IU powder and solvent for solution for injection
# ELOCTA 1000 IU powder and solvent for solution for injection
# ELOCTA 1500 IU powder and solvent for solution for injection
# ELOCTA 2000 IU powder and solvent for solution for injection
# ELOCTA 3000 IU powder and solvent for solution for injection
# ELOCTA 4000 IU powder and solvent for solution for injection

efmoroctocog alfa (recombinant coagulation factor VIII)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


## 1. What ELOCTA is and what it is used for

ELOCTA contains the active substance efmoroctocog alfa, a recombinant coagulation factor VIII, Fc fusion protein. Factor VIII is a protein produced naturally in the body and is necessary for the blood to form clots and stop bleeding.

ELOCTA is a medicine used for the treatment and prevention of bleeding in all age groups of patients with haemophilia A (inherited bleeding disorder caused by factor VIII deficiency).

ELOCTA is prepared by recombinant technology without addition of any human- or animal-derived components in the manufacturing process.

**How ELOCTA works**
In patients with haemophilia A, factor VIII is missing or not working properly. ELOCTA is used to replace the missing or deficient factor VIII. ELOCTA increases factor VIII level in the blood and temporarily corrects the bleeding tendency.

## 2. What you need to know before you use ELOCTA

**Do not use ELOCTA:**
- if you are allergic to efmoroctocog alfa or any other ingredients of this medicine (listed in section 6).

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using ELOCTA.

- There is a small chance that you may experience an anaphylactic reaction (a severe, sudden allergic reaction) to ELOCTA. Signs of allergic reactions may include generalised itching, hives, tightness of the chest, difficulty breathing and low blood pressure. If any of these symptoms occur, stop the injection immediately and contact your doctor.

- The formation of inhibitors (antibodies) is a known complication that can occur during treatment with all factor VIII medicines. These inhibitors, especially at high levels, stop the treatment working properly and you or your child will be monitored carefully for the development of these inhibitors. If your or your child's bleeding is not being controlled with ELOCTA, tell your doctor immediately.

Cardiovascular events
If you have heart disease or are at risk for heart disease, take special care when using factor VIII medicines and talk to your doctor.

Catheter-related complications
If you require a central venous access device (CVAD), risk of CVAD-related complications including local infections, presence of bacteria in the blood and catheter site thrombosis should be considered.

Documentation
It is strongly recommended that every time ELOCTA is given, the name and batch number of the product are recorded.

**Other medicines and ELOCTA**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

**Driving and using machines**
No effects on ability to drive or use of machines have been observed.

**ELOCTA contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'. However, depending on your body weight and dose, you could receive more than one vial. This should be taken into consideration if you are on a controlled sodium diet.

## 3. How to use ELOCTA

Treatment with ELOCTA will be started by a doctor who is experienced in the care of patients with haemophilia. Always use this medicine exactly as your doctor has told you (see Instructions for preparation and administration). Check with your doctor, pharmacist or nurse if you are not sure.

ELOCTA is given as an injection into a vein. Your doctor will calculate the dose of ELOCTA (in International Units or "IU") depending on your individual needs for factor VIII replacement therapy and on whether it is used for prevention or treatment of bleeding. Talk to your doctor if you think that your bleeding is not being controlled with the dose you receive.

How often you need an injection will depend on how well ELOCTA is working for you. Your doctor will perform appropriate laboratory tests to make sure that you have adequate factor VIII levels in your blood.

**Treatment of bleeding**
The dose of ELOCTA is calculated depending on your body weight and the factor VIII levels to be achieved. The target factor VIII levels will depend on the severity and location of the bleeding.

**Prevention of bleeding**
The usual dose of ELOCTA is 50 IU per kg of body weight, given every 3 to 5 days. The dose may be adjusted by your doctor in the range of 25 to 65 IU per kg of body weight. In some cases, especially in younger patients, shorter dosing intervals or higher doses may be necessary.

**Use in children and adolescents**
ELOCTA can be used in children and adolescents of all ages. In children below the age of 12, higher doses or more frequent injections may be needed.

**If you use more ELOCTA than you should**
Tell your doctor as soon as possible. You should always use ELOCTA exactly as your doctor has told you, check with your doctor, pharmacist or nurse if you are not sure.

**If you forget to use ELOCTA**
Do not take a double dose to make up for a forgotten dose. Take your dose as soon as you remember and then resume your normal dosing schedule. If you are not sure what to do, ask your doctor or pharmacist.

**If you stop using ELOCTA**
Do not stop using ELOCTA without consulting your doctor. If you stop using ELOCTA you may no longer be protected against bleeding or a current bleed may not stop.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

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

If severe, sudden allergic reactions (anaphylactic reaction) occur, the injection must be stopped immediately. You must contact your doctor immediately if you experience any of the following symptoms of allergic reactions: swelling of the face, rash, generalised itching, hives, tightness of the chest, difficulty breathing, burning and stinging at the injection site, chills, flushing, headache, low blood pressure, general feeling of being unwell, nausea, restlessness and fast heartbeat, feeling dizzy or loss of consciousness.

For children previously untreated with factor VIII medicines, inhibitor antibodies (see section 2) may form very commonly (more than 1 in 10 patients); however, patients who have received previous treatment with factor VIII (more than 150 days of treatment) the risk is uncommon (less than 1 in 100 patients). If this happens the medicines may stop working properly and you may experience persistent bleeding. If this happens, you should contact your doctor immediately.

The following side effects may occur with this medicine.

**Uncommon side effects (may affect up to 1 in 100 people)**
Headache, dizziness, taste alteration, slow heartbeat, high blood pressure, hot flushes, vascular pain after injection, cough, lower abdominal pain, rash, papular rash, device-related thrombosis, joint swelling, muscle pain, back pain, joint pain, general discomfort, chest pain, feeling cold, feeling hot and low blood pressure.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

**United Kingdom**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store ELOCTA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial label after "EXP". The expiry date refers to the last day of that month. Do not use this medicine if it has been stored at room temperature for longer than 6 months.

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect from light.

Alternatively, ELOCTA may be stored at room temperature (up to 30°C) for a single period not exceeding 6 months. Record on the carton the date that ELOCTA is removed from the refrigerator and set at room temperature. After storage at room temperature, the product must not be put back in the refrigerator.

Once you have prepared ELOCTA it should be used right away. If you cannot use the prepared ELOCTA solution immediately, it should be used within 6 hours. Do not refrigerate the prepared solution. Protect the prepared solution from direct sunlight.

The prepared solution will be clear to slightly opalescent and colourless. Do not use this medicine if you notice that it is cloudy or contains visible particles.

Discard any unused solution appropriately. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What ELOCTA contains

- The active substance is efmoroctocog alfa (recombinant coagulation factor VIII, Fc fusion protein). Each vial of ELOCTA contains nominally 250, 500, 750, 1000, 1500, 2000, 3000 or 4000 IU efmoroctocog alfa.
- The other ingredients are sucrose, sodium chloride, histidine, calcium chloride dihydrate, polysorbate 20, sodium hydroxide, hydrochloric acid and water for injections. If you are on a controlled sodium diet, see section 2.

### What ELOCTA looks like and contents of the pack

ELOCTA is provided as a powder and solvent for solution for injection. The powder is a white to off-white powder or cake. The solvent provided for preparation of the solution to inject, is a clear, colourless solution. After preparation, the solution to inject is clear to slightly opalescent and colourless.

Each pack of ELOCTA contains 1 powder vial, 3 mL solvent in pre-filled syringe, 1 plunger rod, 1 vial adapter, 1 infusion set, 2 alcohol swabs, 2 plasters and 1 gauze pad.

**Marketing Authorisation Holder and Manufacturer**
Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

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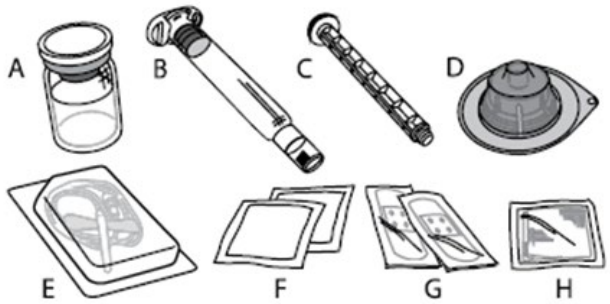
Turn the leaflet over for instructions for preparation and administration

**Instructions for preparation and administration**

ELOCTA is administered by intravenous (IV) injection after dissolving the powder for injection with the solvent supplied in the pre-filled syringe. ELOCTA pack contains:




A) 1 Powder vial
B) 3 mL solvent in pre-filled syringe
C) 1 Plunger rod
D) 1 Vial adapter
E) 1 Infusion set
F) 2 Alcohol swabs
G) 2 Plasters
H) 1 Gauze pad

ELOCTA should not be mixed with other solutions for injection or infusion.

Wash your hands before opening the pack.

**Preparation:**

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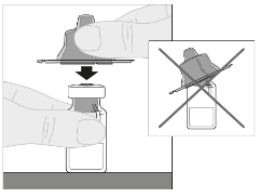
| 1. | Check the name and strength of the package, to make sure it contains the correct medicine. Check the expiry date on the ELOCTA carton. Do not use if the medicine has expired. |
| 2. | If ELOCTA has been stored in a refrigerator, allow the vial of ELOCTA (A) and the syringe with solvent (B) to reach room temperature before use. Do not use external heat. |
| 3. | Place the vial on a clean flat surface. Remove the plastic flip-top cap from the ELOCTA vial.  |
| 4. | Wipe the top of the vial with one of the alcohol swabs (F) provided in the pack, and allow to air dry. Do not touch the top of the vial or allow it to touch anything else once wiped.  |
| 5. | Peel back the protective paper lid from the clear plastic vial adapter (D). Do not remove the adapter from its protective cap. Do not touch the inside of the vial adapter package. |
| 6. | Place the vial on a flat surface. Hold the vial adapter in its protective cap and place it squarely over the top of the vial. Press down firmly until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.  |

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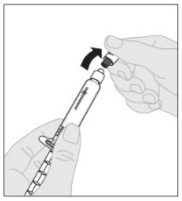
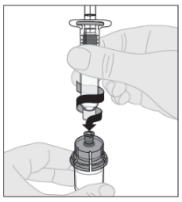
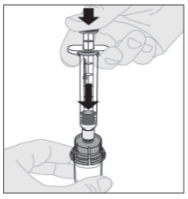
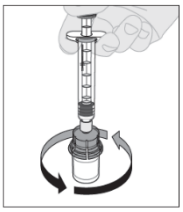
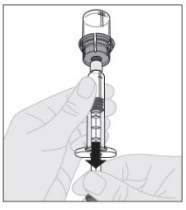
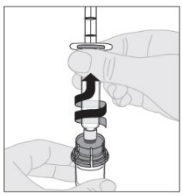
| 7. | Attach the plunger rod (C) to the solvent syringe by inserting the tip of the plunger rod into the opening in the syringe plunger. Turn the plunger rod firmly clockwise until it is securely seated in the syringe plunger. |  |
| 8. | Break off the white, tamper-resistant, plastic cap from the solvent syringe by bending at the perforation cap until it snaps off. Set the cap aside by placing it with the top down on a flat surface. Do not touch the inside of the cap or the syringe tip. |  |
| 9. | Lift the protective cap away from the adapter and discard. |  |
| 10. | Connect the solvent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening. Firmly push and turn the syringe clockwise until it is securely connected. |  |
| 11. | Slowly depress the plunger rod to inject all the solvent into the ELOCTA vial. |  |
| 12. | With the syringe still connected to the adapter and the plunger rod pressed down, gently swirl the vial until the powder is dissolved. Do not shake. |  |
| 13. | The final solution must be inspected visually before administration. The solution should appear clear to slightly opalescent and colourless. Do not use the solution if cloudy or contains visible particles. | |
| 14. | Ensuring that the syringe plunger rod is still fully pressed down, invert the vial. Slowly pull on the plunger rod to draw back all the solution through the vial adapter into the syringe. |  |

15. Detach the syringe from the vial adapter by gently pulling and turning the vial counterclockwise.



Note: If you use more than one vial of ELOCTA per injection, each vial should be prepared separately as per the previous instructions (steps 1 to 13) and the solvent syringe should be removed, leaving the vial adapter in place. A single large luer lock syringe may be used to draw back the prepared contents of each of the individual vials.

16. Discard the vial and the adapter.

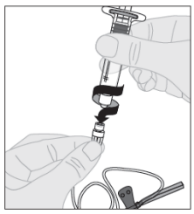
Note: If the solution is not to be used immediately, the syringe cap should be carefully put back on the syringe tip. Do not touch the syringe tip or the inside of the cap.

After preparation, ELOCTA can be stored at room temperature for up to 6 hours before administration. After this time, the prepared ELOCTA should be discarded. Protect from direct sunlight.

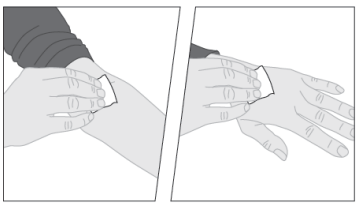
**Administration (Intravenous injection):**

ELOCTA should be administered using the infusion set (E) provided in this pack.

1. Open the infusion set package and remove the cap at the end of the tubing. Attach the syringe with the prepared ELOCTA solution to the end of the infusion set tubing by turning clockwise.



2. If needed apply a tourniquet and prepare the injection site by wiping the skin well with the other alcohol swab provided in the pack.



3. Remove any air in the infusion set tubing by slowly depressing on the plunger rod until liquid has reached the infusion set needle. Do not push the solution through the needle. Remove the clear plastic protective cover from the needle.

4. Insert the infusion set needle into a vein as instructed by your doctor or nurse and remove the tourniquet. If preferred, you may use one of the plasters (G) provided in the pack to hold the plastic wings of the needle in place at the injection site. The prepared product should be injected intravenously over several minutes. Your doctor may change your recommended injection rate to make it more comfortable for you.

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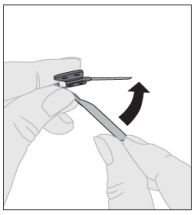
| 5. | After completing the injection and removing the needle, you should fold over the needle protector and snap it over the needle.  |
| 6. | Please safely dispose of the used needle, any unused solution, the syringe and the empty vial in an appropriate medical waste container as these materials may hurt others if not disposed of properly. Do not reuse equipment. |