PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a physician's prescription only

ELOCTA 250, 500, 1000, 2000, 3000 IU

Powder and solvent for solution for injection

The medicine's name, form and strength:
Each vial of powder contains:

Recombinant human coagulation factor VIII (efmoroctocog alfa) 250 IU

Recombinant human coagulation factor VIII (efmoroctocog alfa) 500 IU

Recombinant human coagulation factor VIII (efmoroctocog alfa) 1000 IU

Recombinant human coagulation factor VIII (efmoroctocog alfa) 2000 IU

Recombinant human coagulation factor VIII (efmoroctocog alfa) 3000 IU

After being dissolved in water for injection:

1 ml of **ELOCTA 250 IU** contains approximately 83 IU (250 IU / 3 ml) of recombinant human coagulation factor VIII

1 ml of **ELOCTA 500 IU** contains approximately 167 IU (500 IU / 3 ml) of recombinant human coagulation factor VIII

1 ml of **ELOCTA 1000 IU** contains approximately 333 IU (1000 IU / 3 ml) of recombinant human coagulation factor VIII

1 ml of **ELOCTA 2000 IU** contains approximately 667 IU (2000 IU / 3 ml) of recombinant human coagulation factor VIII

1 ml of **ELOCTA 3000 IU** contains approximately 1000 IU (3000 IU / 3 ml) of recombinant human coagulation factor VIII

Inactive and allergenic ingredients: see section 6 "Additional information" and section 2 "Important information about some of the medicine's ingredients".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult with your physician or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is the medicine intended for?

ELOCTA is intended for the treatment and prophylaxis of bleeding in patients with hemophilia A (congenital coagulation factor VIII deficiency).

Therapeutic group: ELOCTA belongs to a class of bleeding-prevention medicines that contain coagulation factor VIII.

ELOCTA contains the active ingredient recombinant human coagulation factor VIII. Coagulation factor VIII is a protein produced naturally in the body, which is needed for the blood to form clots and stop bleeding. **ELOCTA** is manufactured using recombinant technology, and no human- or animal-derived components are added in the manufacturing process.

In patients with hemophilia A, factor VIII is missing or not working properly. **ELOCTA** is administered to overcome the lack of factor VIII.

ELOCTA increases the level of coagulation factor VIII in the blood, and temporarily corrects the bleeding tendency.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, efmoroctocog alfa, or any of the other ingredients

that this medicine contains.
For a list of inactive ingredients, see section 6 “Additional information”.

Special warnings regarding the use of the medicine
Consult with a physician, pharmacist, or nurse before beginning to take ELOCTA:

- There is a small chance of a sudden severe allergic reaction (anaphylactic reaction) to **ELOCTA**. Signs of an allergic reaction may include generalised itching, hives, tightness of the chest, difficulty breathing and low blood pressure. If any of these symptoms occur, **stop the treatment immediately** and consult a physician.
- 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 from working properly, and you or your child will therefore be carefully monitored to check the levels of these inhibitors. If your or your child’s bleeding is not controlled with **ELOCTA**, consult a physician immediately.

Before starting treatment with ELOCTA, tell your physician if:

- You suffer from heart disease or are at risk for heart disease.
- 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 recommended to record the product’s name and batch number each time **ELOCTA** is used.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform your physician or pharmacist.

Pregnancy, breastfeeding, and fertility:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, consult with a physician before using the medicine.

Driving and using machines:
No effect on driving or the use of machines has been observed.

Important information about some of the medicine’s ingredients:
Sodium – The medicine contains less than 1 mmol (23 mg) of sodium per vial. It is therefore considered to be a “sodium-free” medication. However, depending on your body weight and dose, you may need to be treated with more than a single vial. This should be taken into consideration if you are on a low-sodium diet.

3. How should you use the medicine?

This medicine is intended for all ages.
Treatment with **ELOCTA** will be started by a physician who is experienced in the care of patients with hemophilia A.

Always use the preparation according to the physician’s instructions. Check with your physician or pharmacist if you are not sure about the dosage or treatment method for this medicine.

The dosage and treatment method will be determined by the physician only (see section “Detailed instructions for the preparation and injection of **ELOCTA**”).

This medicine is intended for injection into a vein over several minutes, depending on how comfortable it is for you. The injection rate will be no higher than 10 ml/minute.

The number of units of coagulation factor VIII is expressed in International Units (IU). Your physician will calculate how many units you need depending on whether treatment is needed for bleeding or for prevention of bleeding, and depending on your medical condition. Consult with your physician if you think that your bleeding is not controlled by the routine **ELOCTA** dosage that you are taking.

Your physician will determine the frequency of treatment depending on the therapeutic response to **ELOCTA**. Your physician will perform the relevant laboratory tests to confirm that the dosage administered supplies adequate amounts of factor VIII to your blood.

Treatment of bleeding

The **ELOCTA** dosage 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 **ELOCTA** dosage is 50 IU per kg of body weight, given every 3 to 5 days. Your physician may adjust the **ELOCTA** dosage within the range of 25-65 IU per kg of body weight. In some cases, especially in younger patients, shorter dosing intervals or higher doses may be needed.

The elderly

There is limited experience in patients aged 65 years and over.

Children and adolescents

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

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, consult with a physician as soon as possible. Always use **ELOCTA** according to the physician's instructions. Check with your physician or pharmacist if you are not sure about the dosage or method of treatment for this medicine.

If you forget to take the medicine at the scheduled time, do not take a double dose to make up for the forgotten dose. Take the next dose immediately and resume your regular intervals between doses as recommended by your physician. Consult your physician or pharmacist if you are unsure.

Adhere to the treatment regimen as recommended by your physician.

Do not stop treatment with the medicine without consulting your physician.

If you stop using the medicine, you may no longer be protected against bleeding, or a current bleed may not stop.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine consult your physician.

4. Side effects

As with any medicine, the use of **ELOCTA** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

If a sudden severe allergic reaction (anaphylactic reaction) occurs, the injection must be stopped immediately.

Contact your physician immediately when any of the following symptoms of allergic reactions appears: 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, dizziness or loss of consciousness.

In children who have not previously been treated with preparations containing factor VIII, the formation of inhibitor antibodies (see section 2 "Special warnings regarding the use of the medicine") is very common (more than 1 in 10 patients). However, in patients who have previously been treated with factor VIII (more than 150 days of treatment), the formation of inhibitors is uncommon (less than 1 in 100 patients). In this case, the medicine may stop working properly, and you may experience persistent bleeding. If this happens, you must consult your physician immediately.

Additional side effects

Uncommon side effects – effects that occur in 1-10 users out of 1,000:
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, general feeling of being unwell, and low blood pressure.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking the link "Report adverse effects associated with medications" on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the outer package. The expiry date refers to the last day of that month. Do not use the medicine if it has been stored at room temperature for longer than 6 months.

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

  The medicine may be stored at room temperature (up to 30°C) for a single period of up to 6 months. If the medicine is stored at room temperature, its expiry date will be 6 months from the date that it was removed from the refrigerator, or the expiry date that appears on the package, whichever is earlier. The date that the medicine was removed from the refrigerator and stored at room temperature must be recorded on the package. After storage at room temperature, do not return the medicine to the refrigerator.
- Use the preparation straight away after preparing it (dissolving the powder). If the preparation cannot be used straight away, it should be used within 6 hours, with storage conditions of up to 30°C. Do not store the prepared solution in the refrigerator. Protect the prepared solution from direct sunlight. The prepared solution should be destroyed after 6 hours if it has not been used. According to microbial considerations – the preparation should be used straight away after being dissolved.
- Discard any unused remnants of the solution. Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient, the medicine also contains:

  Sucrose, Sodium chloride, Histidine, Calcium chloride dihydrate, Polysorbate 20, Sodium hydroxide (for pH adjustment), Hydrochloric acid (for pH adjustment).

  Solvent: water for injections

  If you are on a low-sodium diet, see section 2 "Important information about some of the medicine's ingredients".

- **What the medicine looks like and contents of the package:**

ELOCTA is provided as a kit, comprised of powder and solvent for preparing the solution for injection.

The powder is white to off-white in color.

The solvent is a clear colorless solution, in a pre-filled syringe.

After the powder is dissolved, the solution obtained is clear to slightly milky and colourless.

Each pack of **ELOCTA** contains a powder vial, and a syringe pre-filled with solvent, as well as a plunger rod, a vial adapter, an infusion set, 2 alcohol swabs, 2 plasters and a gauze pad.

The items needed for preparation and injection of the solution are supplied in each pack of the preparation.

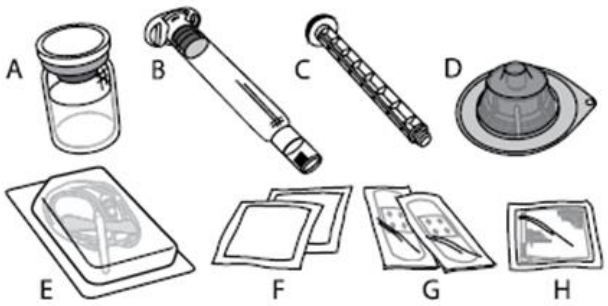
- **Registration holder and address:** MegaPharm Ltd., 15 Ha'tidhar Street, Ra'anana, Israel.
- **Manufacturer name and address:** Swedish Orphan Biovitrum AB (SOBI), Stockholm, Sweden.
- Approved in September 2022 by the Ministry of Health
- Registration number of the medicine in the Israeli Drug Registry of the Ministry of Health:

ELOCTA 250 IU 170-48-36894-00
ELOCTA 500 IU 170-49-36895-00
ELOCTA 1000 IU 170-50-36896-00
ELOCTA 2000 IU 170-51-36898-00
ELOCTA 3000 IU 170-52-36899-00

Detailed instructions for the preparation and injection of ELOCTA

The instructions below describe how to prepare and use **ELOCTA**. Please read these instructions in their entirety before using **ELOCTA**.
ELOCTA is administered by intravenous injection after being dissolved in the solvent supplied in the pre-filled syringe. Each pack contains:

1 powder vial (**A**)
3 ml solvent in pre-filled syringe (**B**)
1 plunger rod (**C**)
1 vial adaptor (**D**)
1 infusion set (**E**)
2 alcohol swabs (**F**)
2 plasters (**G**)
1 gauze pad (**H**)



Do not mix this medicine with other solutions for injection or infusion.

Wash your hands before opening the pack.

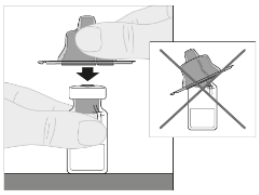
Preparation:

1. Check the name and strength on the package, to make sure it contains the correct medicine. Check the expiry date on the carton package. Do not use if the expiry date that appears on the package has passed.
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 an external heat source.
3. Place the vial on a clean flat surface. Remove the plastic cap from the vial (**A**).

4. Wipe the top of the vial with one of the alcohol swabs (**F**) provided in the pack, and allow to air dry before using. **Do not** touch the top of the vial and **do not** allow any surface or object to touch the top of the vial once it has been wiped.

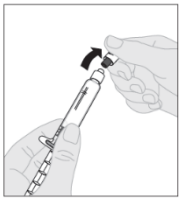
5. Peel back the protective paper lid from the vial adapter (**D**).
Do not remove the adaptor from its plastic wrapping. **Do not** touch the inside part of the adaptor's package.

6. Place the vial on a flat surface. Hold the vial adapter with its plastic wrapping and place it perpendicular to the top of the vial. Press down firmly until the adapter snaps into place on the vial opening, with the adapter spike penetrating the vial stopper.



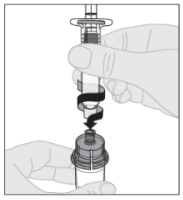
7. Attach the plunger rod (**C**) to the solvent-filled syringe by inserting the tip of the plunger rod into the opening in the syringe plunger. Turn the plunger rod firmly clockwise until it is properly attached to the syringe.

8. Hold the syringe barrel, and break the white plastic cap at the syringe tip by bending the cap until it breaks off. Set the cap aside by placing it, top down, on a flat surface. **Do not** touch the inside part of the cap or the syringe tip.

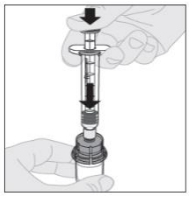


9. Remove the adaptor's wrapping and discard in the waste bin.

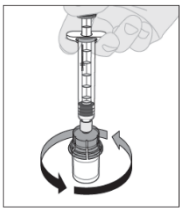
10. Connect the solvent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening. Firmly push the syringe and turn it clockwise until it is properly connected.



11. Slowly depress the plunger rod to inject all the solvent into the powder vial.

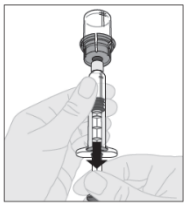


12. With the syringe still connected to the adapter and the plunger rod pressed down, **gently** swirl the vial until all the powder is dissolved. **Do not** shake.

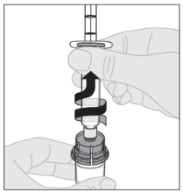


13. Visually inspect the solution obtained before use. The solution should appear clear to slightly milky and colourless. Do not use the solution if it is cloudy or contains visible particles.

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 pulling and gently turning the vial counter clockwise.



Note: If you use more than one vial of **ELOCTA** per injection, each vial should be prepared separately as per the instructions described above (steps 1 to 13). Remove the solvent syringe and leave the vial adaptor in place. A single large luer lock syringe may be used to draw back the prepared solution in each of the individual vials.

16. Discard the vial and the adapter.

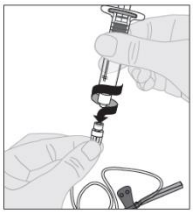
Note: If you do not use the solution immediately, carefully return the syringe cap to the tip of the syringe. Do not touch the syringe tip or the inside of the cap.

After preparation, **ELOCTA** may be stored at room temperature, protected from direct sunlight, for up to 6 hours.
After 6 hours, the prepared solution should be discarded.

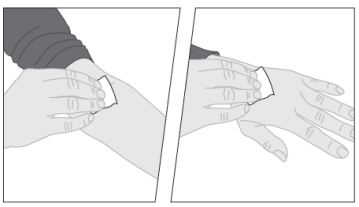
Administration (intravenous injection):

Use the infusion set (**E**) provided in the pack.

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

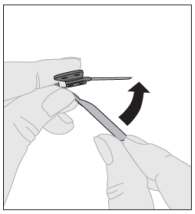


2. Apply a tourniquet if needed and prepare the injection site by cleansing the skin well with the second alcohol swab provided in the pack.



3. Remove any air in the infusion set tubing by slowly pressing the plunger rod until the liquid reaches 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 physician or nurse and remove the tourniquet. If you prefer, 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. Inject the prepared solution into

the vein over several minutes. Your physician may change your recommended injection rate depending on the level of comfort that you experience.
5. After intravenous injection of the preparation and removing the needle, fold the needle protector over and attach it to the needle. 
6. The used needle, any unused solution, the syringe and the empty vial should be disposed of in an appropriate medical waste container, as these items may harm others if not properly disposed.