Package leaflet: Information for the user

ALTUVOCT 250 IU powder and solvent for solution for injection
ALTUVOCT 500 IU powder and solvent for solution for injection
ALTUVOCT 750 IU powder and solvent for solution for injection
ALTUVOCT 1 000 IU powder and solvent for solution for injection
ALTUVOCT 2 000 IU powder and solvent for solution for injection
ALTUVOCT 3 000 IU powder and solvent for solution for injection
ALTUVOCT 4 000 IU powder and solvent for solution for injection

efanesoctocog alfa (recombinant human coagulation factor VIII)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 ALTUVOCT is and what it is used for

ALTUVOCT contains the active substance efanesoctocog alfa, a replacement factor VIII protein.

ALTUVOCT is used to treat and prevent bleeding in patients 2 years and above with severe or moderate haemophilia A (the factor VIII blood level is 5% or less).

Factor VIII is a protein naturally found in the body and is necessary for the blood to form clots and stop bleeding. In patients with haemophilia A, factor VIII is missing or not working properly.

ALTUVOCT replaces the deficient or missing factor VIII. ALTUVOCT increases factor VIII levels in the blood, helping blood to form clots at the site of bleeding which temporarily corrects the bleeding tendency.

2. What you need to know before you use ALTUVOCT

Do not use ALTUVOCT
- if you are allergic to efanesoctocog alfa or any of the other ingredients of this medicine (listed in section 6).

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

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

- Talk to your doctor if you think that your or your child's bleeding is not being controlled with the dose you receive, as there can be several reasons for this. Some people using this medicine can develop antibodies to factor VIII (also known as factor VIII inhibitors). The formation of factor VIII inhibitors 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 be monitored carefully for the development of these inhibitors.

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.

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

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines
ALTUVOCT has no or negligible influence on your ability to drive and use machines.

3. How to use ALTUVOCT

Treatment with ALTUVOCT will be started by a doctor who is experienced in the care of patients with haemophilia A. ALTUVOCT is given as an injection into a vein.

After proper training in the correct injection technique, patients or caregivers may be able to administer ALTUVOCT at home. Your doctor will calculate your dose (in International Units or "IU") for you. This will depend on your weight and whether it is used for prevention or treatment of bleeding.

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Keeping a record
Each time you use ALTUVOCT, record the date, the name of the medicine and the batch number.

Prevention of bleeding
The usual dose of ALTUVOCT is 50 international units (IU) per kg of body weight. The injection is given weekly.

Treatment of bleeding
The dose of ALTUVOCT is 50 international units (IU) per kg of body weight. The dose and frequency may be adjusted depending on the severity and location of the bleeding.

Use in children and adolescents
ALTUVOCT can be used in children 2 years and above, the dose recommendation is the same as in adults.

How ALTUVOCT is given
ALTUVOCT is given as an injection into a vein. See 'Instructions on how to use ALTUVOCT' for more information.

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

If you forget to use ALTUVOCT
Do not inject a double dose to make up for a forgotten dose. Inject 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, pharmacist, or nurse.

If you stop using ALTUVOCT
If you stop using ALTUVOCT you may no longer be protected against bleeding or a current bleed may not stop. Do not stop using ALTUVOCT without talking to your doctor.

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

4. Possible side effects

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

If an anaphylactic reaction occurs, the injection must be stopped immediately, and you must contact your doctor right away.

Symptoms of an anaphylactic reaction include:

- 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
- loss of consciousness

Risk of formation of inhibitors
For children not previously treated with factor VIII medicines, formation of inhibitor antibodies (see section 2) is very common (may affect more than 1 in 10 patients); however, for patients who have received previous treatment with factor VIII (more than 150 days of treatment) the risk is uncommon (may affect up to 1 in 100 patients). If you or your child develop inhibitor antibodies, the medicine may stop working properly and you or your child may experience persistent bleeding. If this happens, you should contact your doctor immediately.

The following side effects may occur with this medicine.

Very common side effects (may affect more than 1 in 10 people)
- headache
- arthralgia (joint pain)

Common side effects (may affect up to 1 in 10 people)
- pain in extremity (arms, hands, legs or feet
- back pain
- eczema (itchy, red or dry skin
- rash
- urticaria (itchy rash)
- fever
- vomiting

Uncommon side effects (may affect up to 1 in 100 people)
- reactions at the injection site (including bruising and inflammation)

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 ALTUVOCT

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 on the vial after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Before ALTUVOCT powder is reconstituted it may be kept at room temperature (≤ 30 °C) for a single period no longer than 6 months. The date that the product is removed from refrigeration should be recorded on the carton. After storage at room temperature, the product must not be put back in the refrigerator.

Do not use beyond the expiry date printed on the vial or six months after removing the carton from refrigeration, whichever is earlier.

Once you have dissolved the ALTUVOCT powder in the solvent provided in the pre-filled syringe it should be used right away. Do not refrigerate the prepared solution.

After reconstitution the solution should be clear and colourless to slightly opalescent. Do not use this medicine if you notice that it is cloudy or contains visible particles.

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 ALTUVOCT contains

- The active substance is efanesoctocog alfa (recombinant human coagulation factor VIII). Each vial of ALTUVOCT contains nominally 250, 500, 750, 1 000, 2 000, 3 000 or 4 000 IU efanesoctocog alfa.
- The other ingredients are sucrose, calcium chloride dihydrate, histidine, arginine hydrochloride, polysorbate 80.

What ALTUVOCT looks like and contents of the pack

ALTUVOCT 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 and colourless to slightly opalescent.

Each pack of ALTUVOCT contains 1 powder vial, 3 mL solvent in pre-filled syringe, 1 plunger rod, 1 vial adapter, and 1 infusion set.

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

Manufacturer
Swedish Orphan Biovitrum AB (publ)
Norra Stationsgatan 93
113 64 Stockholm
Sweden

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Turn the leaflet over for instruction for preparation and administration.

Instructions on how to use ALTUVOCT

READ THESE INSTRUCTIONS CAREFULLY BEFORE USING ALTUVOCT

ALTUVOCT is administered by intravenous injection after dissolving the powder for injection with the solvent supplied in the pre-filled syringe.

If your dose requires multiple vials, you will be provided with multiple packs and ideally a large syringe.

Your healthcare professional should show you how to prepare and inject ALTUVOCT properly before you use it for the first time. Ask your healthcare professional if you have any question.

Important Information

Check you have the correct product name and strength and are aware of the dosing frequency for ALTUVOCT.

Do not use if the medicine has expired, has been opened or appears damaged.

ALTUVOCT should not be mixed with other solutions for injection.

ALTUVOCT should ideally be stored in the refrigerator. Allow the vial and solvent syringe to reach room temperature before use. Do not use external heat.

Check all parts for damage before use, do not use if they appear damaged.

All parts are single use only.

Wash your hands and clean a flat surface before kit preparation. Place syringe safely on a clean surface when not being handled.

Guide to parts (included in the carton)

ALTUVOCT is reconstituted by dissolving the powder for injection (A) in the solvent supplied in the pre-filled syringe (B). ALTUVOCT solution should then be administered using the infusion set (E).

A. Powder vial

B. 3 mL syringe (pre-filled with solvent)

C. Plunger rod

D. Vial adaptor

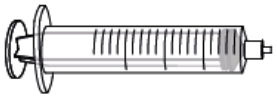
E. Infusion set

Additional parts (not included in the carton)

Ensure you have alcohol swabs (F) available.

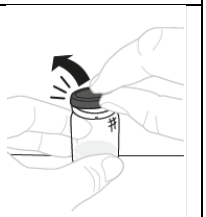
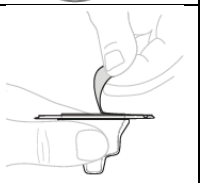
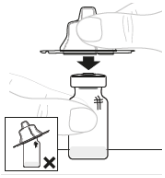
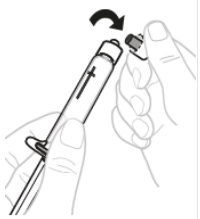
Your pharmacist may have provided a separate large syringe (G) to draw up the solution from multiple vials into a single syringe. If a large syringe is NOT provided, follow steps 6 to 8 to administer the solution from each syringe.

F. Alcohol swabs



G. Large Syringe

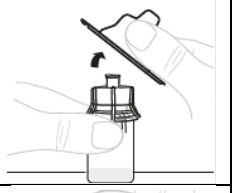
Reconstitution

1. <u>Prepare the vial</u>	
a. **Remove the vial cap** Hold the powder vial (A) on a clean flat surface and remove the plastic cap.	
b. **Clean vial top** Wipe the top of the vial with an alcohol swab. After cleaning, ensure nothing touches the top of the vial.	
c. **Open vial adapter package** Peel off the protective paper lid from the vial adapter package (D). **Do not touch the vial adapter, or remove it from its package.**	
d. **Attach vial adapter** Place the vial adapter package squarely over the top of the vial. Press down firmly until the adapter snaps into place. The spike will penetrate the vial stopper.	
2. <u>Prepare the syringe</u>	
a. **Attach plunger rod** Insert the plunger rod (C) into the 3 mL syringe (B). Turn the plunger rod clockwise until it is securely attached.	
b. **Remove syringe cap** Snap off the top part of white 3 mL syringe cap at the perforations and set aside. ⚠ **Do not touch the inside of cap or the syringe tip.**	

3. <u>Attach syringe to vial</u>

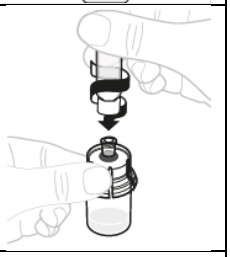
a. **Remove vial adapter package**

Lift the package away from the vial adapter and dispose.



b. **Attach syringe to vial adapter**

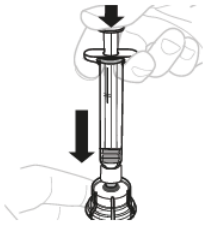
Hold the vial adapter at the lower end. Place the syringe tip onto the top of the vial adapter. Turn the syringe clockwise to securely attach.



4. <u>Dissolve the powder and solvent</u>

a. **Add solvent to vial**

Slowly press the plunger rod to inject all the solvent into the vial.



b. **Dissolve powder**

With your thumb on the plunger rod, gently swirl the vial until powder is dissolved.

Do not shake.

c. **Inspect solution**

Inspect the solution before administration. It should be clear and colourless.

Do not use the solution if cloudy or contains visible particles.

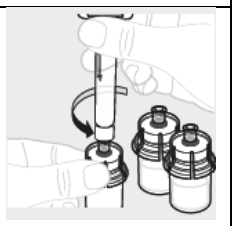
5. <u>If using multiple vials</u>

If your dose requires multiple vials, follow the steps below (5a and 5b) otherwise skip to step 6.

a. **Repeat 1 to 4**

Repeat steps 1 to 4 with all vials until you have prepared enough solution for your dose.

Remove the 3 mL syringes from each vial (see step 6b), leaving the solution in each vial.



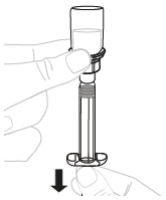
b. **Using large syringe (G) provided by pharmacist**

For each vial, attach the large syringe (G) to the vial adapter (see step 3b) and perform step 6, to combine the solution from each vial into the large syringe. In case you only need part of an entire vial, use the scale on the syringe to see how much solution you withdraw, as instructed by your healthcare professional.

6. Draw solution into syringe

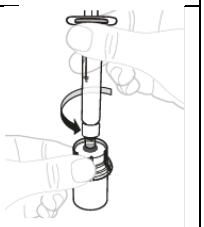
a. **Draw back solution**

Point the syringe up. Slowly pull the plunger rod to draw all the solution into the syringe.



b. **Detach syringe**

Detach the syringe from the vial by holding the vial adapter. Turn the syringe anticlockwise to detach.



Administration

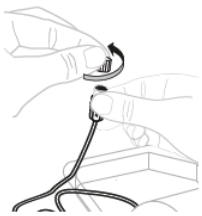
7. Prepare for injection

a. **Remove tubing cap**

Open infusion set (E) packaging (do not use if damaged).

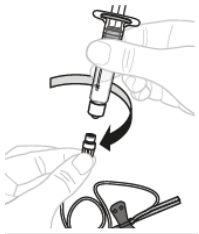
Remove the tubing cap.

⚠ **Do not touch the exposed end of the tubing set.**



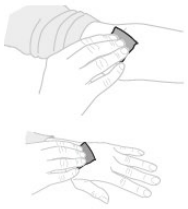
b. **Attach syringe**

Attach prepared syringe to the end of the infusion set tubing by turning the syringe clockwise.



c. **Prepare injection site**

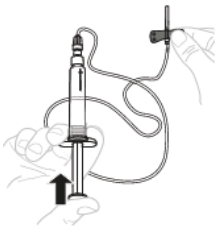
If needed apply a tourniquet. Wipe injection site with an alcohol swab (F).



d. **Remove air from syringe and tubing**

Remove air by pointing the syringe up and gently pressing the plunger rod. Do not push the solution through the needle.

⚠ **Injecting air into the vein can be dangerous.**

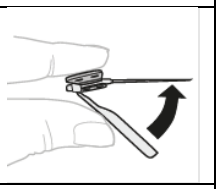


8. Inject solution

a. **Insert needle**

Remove protective needle cover.

Insert the needle into a vein as instructed by your doctor or nurse and remove the tourniquet if used.

	❗ You may use a plaster to hold the plastic wings of the needle in place at the injection site to prevent movement.
b.	**Inject solution** The prepared solution should be injected intravenously over 1 to 10 minutes, based on your comfort level.
9.	**<u>Dispose safely</u>**
a.	**Remove needle** Remove the needle. Fold over the needle protector; it should snap into place. 
b.	**Safe disposal** Safely dispose of the used needle, any unused solution, the syringe and the empty vial in an appropriate medical waste container. ⚠ Do not reuse equipment.