Package leaflet: Information for the user

CEVENFACTA 1 mg (45 KIU) powder and solvent for solution for injection
CEVENFACTA 2 mg (90 KIU) powder and solvent for solution for injection
CEVENFACTA 5 mg (225 KIU) powder and solvent for solution for injection
eptacog beta (activated)

▼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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CEVENFACTA is and what it is used for
2. What you need to know before you use CEVENFACTA
3. How to use CEVENFACTA
4. Possible side effects
5. How to store CEVENFACTA
6. Contents of the pack and other information
7. CEVENFACTA Instructions For Use

1. What CEVENFACTA is and what it is used for

CEVENFACTA contains the active substance eptacog beta (activated), a recombinant human coagulation Factor VIIa (rhFVIIa).

CEVENFACTA is used in adults and adolescents (12 years of age or older) who were born with haemophilia A or B and who have developed inhibitors (antibodies). It is used for:
- the treatment of bleeding episodes,
- the management of bleeding during surgery.

How CEVENFACTA works
This medicine works by making the blood clot at the site of bleeding, when the body's own clotting factors are not working.

2. What you need to know before you use CEVENFACTA

Do not use CEVENFACTA
- if you are allergic to eptacog beta (activated), or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to rabbits or rabbit proteins.

Warnings and precautions
Before treatment with CEVENFACTA, tell your doctor:
- If you have a history of atherosclerosis (when your arteries are narrowed by disease), coronary artery disease (heart disease due to narrowing of the blood vessels supplying the heart),

cerebrovascular disease (disease of the blood vessels supplying the brain), a crush injury, septicaemia (serious blood infection) or blood clots;
- If you have heart disease, heart failure, abnormal heart rhythms;
- If you had prior pulmonary (lungs) clots or heart surgery;
- If you have or have had any other medical condition.

Patients with known allergy to casein may be at a higher risk of hypersensitivity reactions. Should signs or symptoms of hypersensitivity occur, treatment should be discontinued and you should seek immediate medical attention. Symptoms may include hives (itchy swellings under the skin), itching, rash, difficulty breathing, swelling around the mouth and throat, tightness of the chest, wheezing, dizziness or fainting, and low blood pressure.

Although the following conditions have not been observed, they may occur with CEVENFACTA:
- Blood clots in arteries in the heart (which could lead to a heart attack or angina), in the brain (which could lead to a stroke), or in the lungs or deep veins. Symptoms may include swelling and pain in the arms, legs or abdomen, chest pain, shortness of breath, loss of feeling or movement, and altered consciousness or speech.
- Hypersensitivity or anaphylactic reactions. Symptoms may include hives (itchy swellings under the skin), itching, rash, difficulty breathing, swelling around the mouth and throat, tightness of the chest, wheezing, dizziness or fainting, and low blood pressure.
- Inhibitors (antibodies) which may cause bleeding problems.

If any of these conditions apply to you, talk to your doctor before using CEVENFACTA.

It is important to keep a record of the batch number of your CEVENFACTA. So, every time you get a new package of CEVENFACTA, note down the date and the batch number (which is on the packaging after Lot) and keep this information in a safe place.

Adolescents
The listed warnings and precautions apply both to adults and adolescents (12 years of age and older).

Other medicines and CEVENFACTA
Tell your doctor if you are taking, have recently taken or might take any other medicines.

You should talk to your doctor before using CEVENFACTA if
- you are taking or have recently taken another activated Factor VII, or activated or non-activated prothrombin complex concentrates,
- you are taking or have recently taken Factor XIII,

since the combination of these medicines with CEVENFACTA may increase the risk of thromboembolic events (formation of blood clots in the veins).

You should talk to your doctor before using CEVENFACTA with these 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
Dizziness might occur following administration of CEVENFACTA. You must avoid driving or using machines while experiencing this symptom.

CEVENFACTA contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per injection, that is to say essentially ‘sodium free’.

3. How to use CEVENFACTA

Treatment with this medicine should be initiated and supervised by a physician experienced in the treatment of haemophilia and/or bleeding disorders.
CEVENFACTA comes as a powder that must be made up (reconstituted) with its solvent and injected into a vein (intravenous injection). See instructions for use guide at the end of this leaflet (section 7).

When to treat yourself
Injecting medicines requires special training. Do not attempt to self-inject unless you have been taught how to by your healthcare provider or haemophilia treatment centre.

Many people with inhibitors learn to self-inject or inject with the help of a family member: once trained, you will need additional injection equipment along with your CEVENFACTA kit so that you can successfully treat your bleeding episodes at home. Be sure to collect all necessary injection equipment before preparing the medicine for injection. This additional injection equipment will be provided by your healthcare professional (e.g., your pharmacist or haemophilia treatment centre).

CEVENFACTA may be injected at a haemophilia treatment centre, at your healthcare provider's office, or at home. Treating at the first sign of a bleed is important for bleed management.

Start treatment of a bleed as early as possible, ideally within 2 hours.
• In cases of a mild or moderate bleed (e.g., joint, superficial muscle, soft tissue, and mucous membranes), you should treat yourself as early as possible, ideally at home.
• In case of a severe bleed (e.g., life or limb [arm or leg] threatening haemorrhage, intracranial [within the skull] or gastrointestinal [in the stomach or gut] haemorrhage) you should contact your doctor.

Usually, severe bleeds are treated at the hospital and a dose of CEVENFACTA can be given on the way there.

Do not treat yourself for longer than 24 hours without consulting your doctor.
• Each time you use this medicine tell your healthcare provider as soon as possible.
• If bleeding is not controlled within 24 hours, contact your healthcare provider or emergency services immediately. You will usually need hospital care.

For instructions on reconstitution of the medicinal product before administration, follow the **Instructions For Use** guide at the end of this leaflet (section 7).
Inject the solution into your vein over 2 minutes or less.

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

Dose
Your healthcare provider will tell you how much CEVENFACTA to use, and when to use this medicine based on your weight, condition and type of bleed.

Treatment of bleeding episodes
Treatment with this medicine should be started as soon as a bleeding event occurs.

<u>Mild and moderate bleeding</u>

For mild to moderate bleeding episodes, treatment at home should not last longer than 24 hours. Continuing home treatment after 24 hours can only be considered after consultation with the haemophilia treatment centre.

Severe bleeding

You should seek immediate medical care if signs or symptoms of severe bleeding occur at home. An initial dose can be administered on your way to the haemophilia treatment centre or your healthcare provider's office to avoid any treatment delay.

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

Method of administration
For instructions on reconstitution of the medicinal product before administration and instructions on administration, follow the **Instructions For Use** guide at the end of this leaflet (section 7).

If you use more CEVENFACTA than you should
If you use too much CEVENFACTA, get medical advice at once.

If you forget to use CEVENFACTA,
If you forget to use CEVENFACTA, talk 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.

Common side effects
(may affect up to 1 in 10 people)
- Dizziness
- Headache
- Injection site discomfort
- Injection site bruising (haematoma)
- Body temperature increased
- Post procedural haematoma
- Injection related reaction

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

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 label and the carton after EXP. The expiry date refers to the last day of that month.

Store below 30 °C.
Do not freeze.

Keep the vial in the outer carton in order to protect from light.

To reconstitute CEVENFACTA only use the material provided in the kit.

After reconstitution, the product must be stored below 30 °C in the original vial and given within 4 hours. Do not freeze.

Any unused solution should be thrown away 4 hours after reconstitution.
Do not use this medicine if you notice the liquid has particles or is cloudy after mixing.

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 CEVENFACTA contains
- The active substance is recombinant coagulation factor VIIa (eptacog beta (activated))
- The other excipients are:
  Powder: arginine hydrochloride, isoleucine, trisodium citrate dihydrate, glycine, lysine hydrochloride, polysorbate 80, hydrochloric acid (for pH adjustment).
  Solvent: water for injections.
  See section 2 "CEVENFACTA contains sodium".

The powder for solution for injection contains: 1 mg/vial (corresponding to 45 KIU/vial), 2 mg/vial (corresponding to 90 KIU/vial), 5 mg/vial (corresponding to 225 KIU/vial).
After reconstitution the solution concentration is approximately 1 mg/ mL (45 KIU/ mL) eptacog beta (activated). 1 KIU equals 1 000 IU (International Units).

What CEVENFACTA looks like and contents of the pack
The powder vial contains a white to off-white lyophilised powder and the prefilled syringe of solvent contains clear and colourless solution. The reconstituted solution should be clear to slightly opaque.

Each CEVENFACTA pack contains:
- 1 glass vial with powder for solution for injection,
- 1 sterile vial adapter for reconstitution equipped with a 5 µm filter,
- 1 prefilled syringe of water for injections,
- 1 plunger rod and backstop.

Pack sizes: 1 mg (45 KIU), 2 mg (90 KIU), and 5 mg (225 KIU).

Marketing Authorisation Holder
Laboratoire français du Fractionnement et des Biotechnologies
Tour W
102 Terrasse Boieldieu 19ème Étage
92800 Puteaux
France

Manufacturer
LFB Biotechnologies
Zone d'activité de Courtabœuf
3 Avenue des Tropiques
91940 Les Ulis
France
+33 1 69 82 70 10

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
LFB Biopharmaceuticals Ltd
Suite 106, Spirella Building, Bridge Road,
Letchworth Garden City,
Hertfordshire, SG6 4ET
Tel: +44 1462 55 8844

e-mail: medinfo.uk@pharmalex.com

This leaflet was last revised in March 2025

Other sources of information

INSTRUCTIONS FOR USE:

READ THESE INSTRUCTIONS CAREFULLY BEFORE YOU START USING CEVENFACTA

CEVENFACTA is supplied as a powder. Before injection it must be made up (reconstituted) with the solvent supplied in the syringe. The solvent is water for injections. The reconstituted CEVENFACTA must be injected into your vein (intravenous use only).

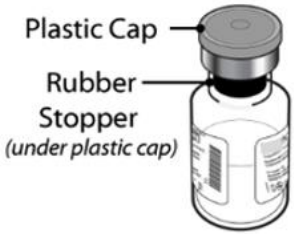
This kit provides the equipment needed to reconstitute this medicine. Additional materials are needed to inject the medicine after reconstitution. These materials will be provided by your healthcare professional (e.g., your pharmacist or haemophilia treatment centre).

Your doctor or your nurse will show you and/or your caregiver how to make up and inject CEVENFACTA. Do not use this kit without proper training by your healthcare provider or haemophilia treatment centre.

Use a clean and germ-free (aseptic) technique when preparing and injecting the medicine.

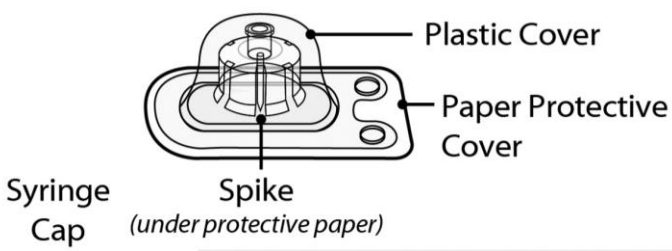
Your CEVENFACTA kit contains:
- 1 glass vial with powder for solution for injection
- 1 sterile vial adapter for reconstitution equipped with a 5 µm filter
- 1 prefilled syringe of water for injections
- 1 plunger rod and backstop

Powder Vial

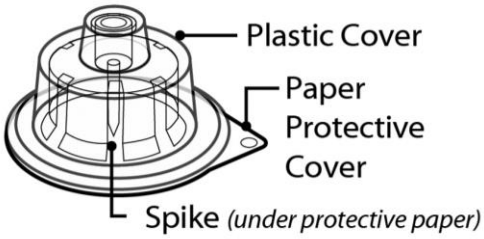


Vial Adapters* and Packaging

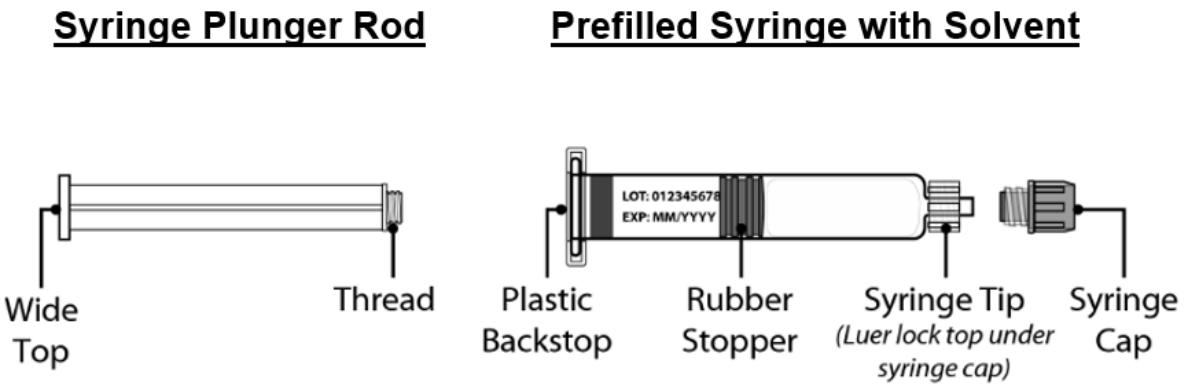
1mg and 2mg Vial Adapter



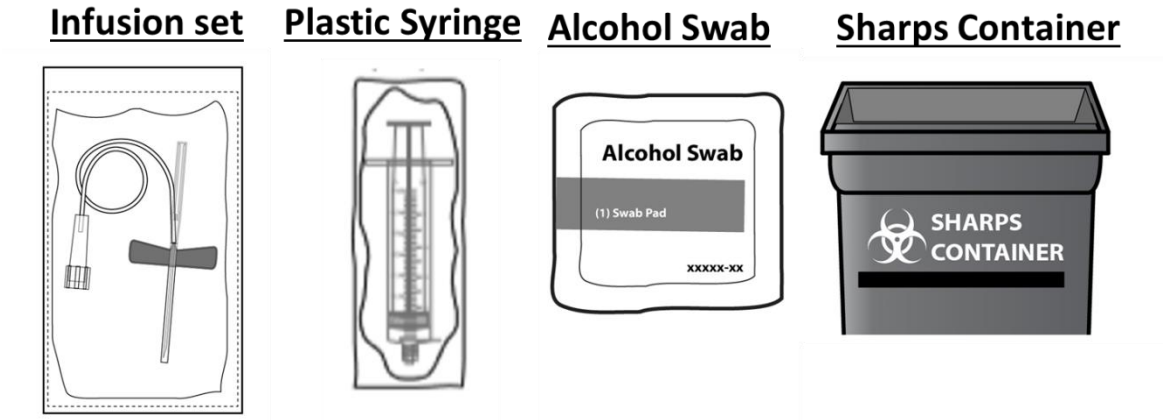
5mg Vial Adapter



**NOTE: Your CEVENFACTA kit will contain only one vial adapter.*



You will also need a sterile injection set (tubing and butterfly needle), a sterile plastic syringe, sterile alcohol swabs and a sharps container compliant with local applicable regulations and standards**. These materials are not included in the CEVENFACTA package.** These additional materials will be provided by your healthcare professional (e.g., your pharmacist or haemophilia treatment centre).



1) Collect equipment and prepare vial

- Take out the number of CEVENFACTA kits you need to fulfill your prescribed dose, a sterile injection set (not supplied) and an alcohol swab (not supplied).

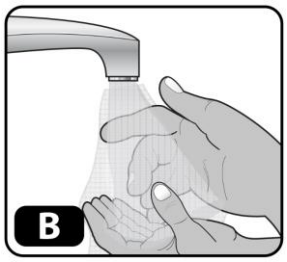
Do not use the kit if the tamper seal has been broken or you suspect the kit is contaminated. Use a new kit instead.

- Check the expiry date on the side of the kit **(Fig. A)**.

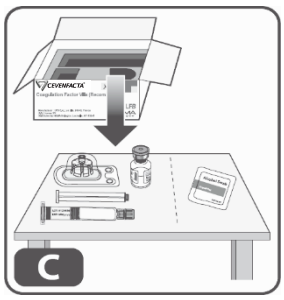
Do not use if the expiry date has passed.

- Check the name, strength and colour of the package to make sure it contains the correct product (1 mg package is yellow, 2 mg package is green and 5 mg package is purple).

- Clean a flat surface before starting the steps for reconstituting CEVENFACTA.
- Wash your hands with soap and water and dry using a clean towel or air dry **(Fig. B)**.



- Take out the contents of one kit and one alcohol swab. Place items on the clean surface **(Fig. C)**.



- Inspect all contents of the kit. Make sure each vial has a matching coloured syringe.

Do not use the contents if they have been dropped or if they are damaged. Use a new kit instead.

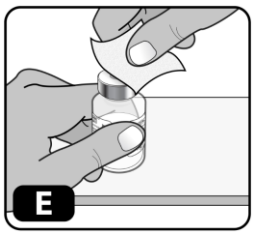
- If not already at room temperature, bring the vial and the pre-filled syringe to room temperature. You can do this by holding them in your hands until they feel as warm as your hands.

Do not warm the vial and pre-filled syringe in any other way.

- Remove the plastic cap from the vial **(Fig. D).**

If the plastic cap is loose or missing, do not use the vial.

- Wipe the rubber stopper with an alcohol swab **(Fig. E)** and allow it to air dry for a few seconds to ensure that it is as germ free as possible.

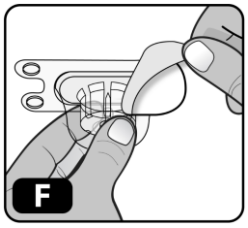


- After cleaning with the swab, **do not touch the rubber stopper with your fingers and do not allow it to touch any other object** until you attach the vial adapter, as this can transfer germs.

2) Attach vial adapter

- Peel off the protective paper cover from the vial adapter package **(Fig. F)**.

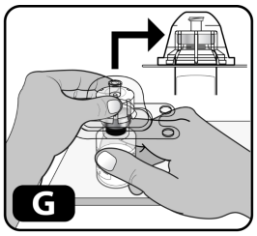
If the protective paper cover is not fully sealed or if it is broken, do not use the vial adapter.



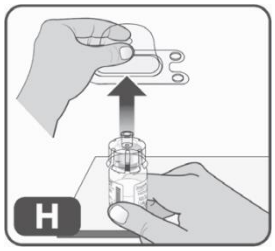
Do not take the vial adapter out of the protective cap with your fingers. If you touch the spike on the vial adapter, you may transfer germs from your fingers onto the spike.

- Place the vial on a clean flat surface and hold with one hand. Use your other hand to hold the plastic cover (with the vial adapter inside) directly over the vial and line up the spike of the adapter with the middle of the grey rubber stopper.

- Firmly press the plastic cover down so that the vial adapter spike breaks through the rubber stopper (you may hear/see it "snap" into place) **(Fig. G).**



- Lightly squeeze the plastic cover and lift it up to remove it from the vial adapter **(Fig. H)**.



Do not touch the top of the vial adapter once you have removed plastic cover to avoid transferring germs from your fingers.

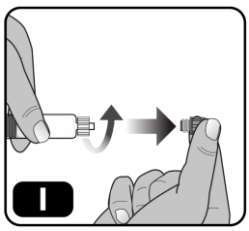
NOTE: The 5 mg vial adapter may not sit flat against the vial, but it is fully functional. As mentioned previously, your CEVENFACTA kit will contain only one vial adapter: the one suitable for the vial included in the kit.

3) Attach pre-filled syringe and install the plunger rod

- Remove the syringe cap from the pre-filled syringe by holding the syringe body with one hand and using the other hand to unscrew the syringe cap (turn to the left) **(Fig. I)**.

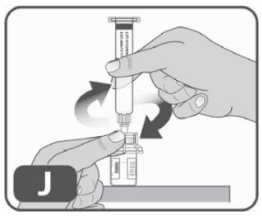
Do not touch the syringe tip under the syringe cap to avoid transferring germs from your fingers.

Do not use the pre-filled syringe if the syringe cap is loose or missing.



- Hold the edges of the vial adapter and screw on the pre-filled syringe (turn to the right a few times) until it starts to tighten **(Fig. J)**.

Be careful not to overtighten as you will need to remove the syringe later.



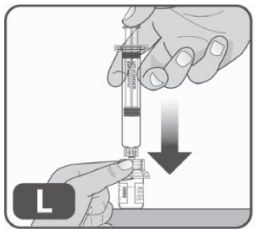
- To attach the plunger rod onto the syringe, hold the wide top end of the plunger rod in one hand and the syringe body in your other hand.

- Insert the plunger rod into the syringe, then screw a few turns (turn to the right) so that the plunger rod is attached to the grey rubber stopper in the syringe **(Fig. K)**.

4) Mix medicinal product in vial

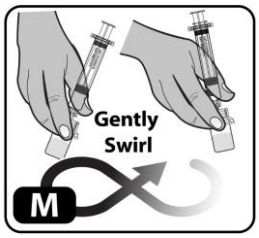
- Very slowly push the plunger rod down to the bottom of the syringe, to transfer all of the liquid from the syringe into the vial **(Fig. L)**.

Do not push too quickly as it can result in excess foam in the vial.



- Swirl the vial gently or roll between hands until all powder is dissolved **(Fig. M)**.

Do not shake the vial as this creates foam.

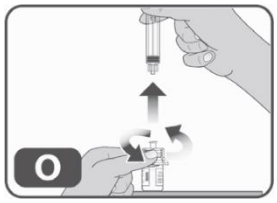


- Check the mixed solution **(Fig. N)**. It should be clear to slightly opaque. All powder should be dissolved with no particles floating in the liquid.

Do not use the medicinal product if the liquid has particles or is cloudy after mixing. Start over with a new kit.

5) Remove empty syringe from vial adapter

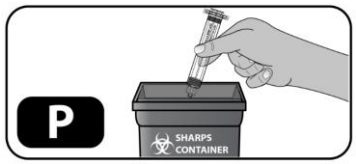
- Without withdrawing any medicinal product back into the syringe, unscrew the syringe from the vial adapter (turn to the left) until it is completely detached **(Fig. O)**.



- Throw out the empty syringe into an approved sharps container **(Fig. P)**.

Do not remove the vial adapter.

Do not touch the luer lock top of the vial adapter. If you touch this top, you may transfer germs from your fingers.



6) Mix additional vial(s) and inject dose

- If your dose requires more than one vial, repeat the above steps with additional kits until you have reached your required dose.

- Withdraw the liquid medicinal product from the vial(s), using a sterile syringe provided by your pharmacy that is large enough to hold your prescribed dose.

- CEVENFACTA must be administered within 4 hours of reconstitution **(Fig. Q)**.

Do not use if more than 4 hours have passed since reconstitution.

- CEVENFACTA can be given as an injection into your vein over the course of 2 minutes or less, according to the instructions given by your healthcare provider.

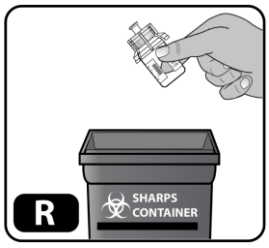
7) Throw out empty medicinal product vial(s)

- After reconstitution and injection, safely dispose of the vial with the vial adapter attached, the injection syringe, and any other waste materials into an approved sharps container **(Fig. R)**.

Do not throw out with ordinary household waste.

Do not take the vial and vial adapter apart before disposal.

Do not reuse any components of the kit.



Follow local applicable regulations and standards for proper disposal of the sharps container.

Storage

CEVENFACTA is supplied in a kit that should be stored below 30 °C.
Do not open the kit contents until you are ready to use them.
Do not freeze or store syringes containing reconstituted CEVENFACTA solution.
Avoid exposure of the reconstituted CEVENFACTA solution to direct light.

Important information

CEVENFACTA is only for injection into a vein (intravenous administration). Do not inject in any other way such as below the skin (subcutaneously) or into a muscle (intramuscularly). Contact your doctor, nurse or pharmacist if you experience problems.