Package Leaflet: Information for the user

Kovaltry 250 IU powder and solvent for solution for injection
Kovaltry 500 IU powder and solvent for solution for injection
Kovaltry 1000 IU powder and solvent for solution for injection
octocog alfa (recombinant human 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kovaltry is and what it is used for

Kovaltry contains the active substance human recombinant coagulation factor VIII, also called octocog alfa. Kovaltry is prepared by recombinant technology without addition of any human- or animal derived components in the manufacturing process. Factor VIII is a protein naturally found in the blood that helps to clot it.

Kovaltry is used to **treat and prevent bleeding** in adults, adolescents and children of all ages with haemophilia A (hereditary factor VIII deficiency).

2. What you need to know before you use Kovaltry

Do not use Kovaltry if you are
- allergic to octocog alfa or to any of the other ingredients of this medicine (listed in section 6).
- allergic to mouse or hamster proteins.

Warnings and precautions
Talk to your doctor or pharmacist if you have:
- tightness in the chest, dizziness (including when you get up from sitting or lying down), itchy nettle-rash, wheezing, feeling sick or faint. These may be signs of a rare severe sudden allergic reaction to Kovaltry. **Stop administering the product** immediately and seek medical advice if this occurs.
- bleeding that is not being controlled with your usual dose of Kovaltry. 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, patients receiving Kovaltry will be monitored carefully for the development of these inhibitors. If your or your child's bleeding is not being controlled with Kovaltry, tell your doctor immediately.
- previously developed factor VIII inhibitors to a different product. If you switch factor VIII products, you may be at risk of your inhibitor coming back.

- a confirmed heart disease or are at risk of heart disease.
- to use a central venous access device for the administration of Kovaltry. You may be at risk of device related complications where the catheter is inserted including:
  - local infections
  - bacteria in the blood
  - a blood clot in the blood vessel.

Children and adolescents
The listed warnings and precautions apply to patients of all ages, adults and children.

Other medicines and Kovaltry
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 for advice before using this medicine.

Kovaltry is not likely to affect the fertility in male or female patients, as the active substance is naturally occurring in the body.

Driving and using machines
If you experience dizziness or any other symptoms affecting your ability to concentrate and react, do not drive or use machines until the reaction subsides.

Kovaltry contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Kovaltry

Treatment with Kovaltry will be started by a doctor who is experienced in the care of patients with haemophilia A. Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
The number of factor VIII units is expressed in International Units (IU).

Treatment of bleeding
To treat a bleed, your doctor will calculate and adjust your dose and how often it should be given, depending on factors such as:
- your weight
- the severity of your haemophilia A
- where the bleed is and how serious it is
- whether you have inhibitors and how high their level is
- the factor VIII level that is needed.

Prevention of bleeding
If you are using Kovaltry to prevent bleeding, your doctor will calculate the dose for you. This will usually be in the range of 20 to 40 IU of octocog alfa per kg of body weight, injected two or three times per week. However, in some cases, especially for younger patients, shorter dose intervals or higher doses may be necessary.

Laboratory tests
Laboratory tests at suitable intervals help to ensure you always have adequate factor VIII levels. For major surgery in particular, your blood clotting must be closely monitored.

Use in children and adolescents
Kovaltry can be used in children of all ages. In children below the age of 12 higher doses or more frequent injections than prescribed for adults may be needed.

Patients with inhibitors
If you have been told by your doctor that you have developed factor VIII inhibitors you may need to use a larger dose of Kovaltry to control bleeding. If this dose does not control your bleeding your doctor may consider giving you another product.
Speak to your doctor if you would like further information on this.
Do not increase the dose of Kovaltry to control your bleeding without checking with your doctor.

Duration of treatment
Usually, Kovaltry treatment for haemophilia is needed life-long.

How Kovaltry is given
Kovaltry is injected into a vein over 2 to 5 minutes depending on the total volume and your comfort level and should be used within 3 hours after reconstitution.

How Kovaltry is prepared for administration
Use only the components (vial adapter, pre filled syringe containing solvent and venipuncture set) provided with each package of this medicine. Please contact your doctor if these components cannot be used. Do not use if any component of the package is opened or damaged.

The reconstituted product **must be filtered by using the vial adapter** before administration to remove any possible particles in the solution.

Do not use the venipuncture set provided for drawing blood because it contains an in-line filter.

This medicine must **not** be mixed with other infusion solutions. Do not use solutions containing visible particles or that are cloudy. Follow the instructions for use given by your doctor **and provided at the end of this leaflet.**

If you use more Kovaltry than you should
Tell your doctor if this occurs. No cases of overdose have been reported.

If you forget to use Kovaltry
Administer your next dose immediately and continue at regular intervals as advised by your doctor.
Do not use a double dose to make up for a forgotten dose**.**

If you stop using Kovaltry
Do not stop using this medicine without checking with 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.

The most **serious** side effects are **allergic reactions** which may be severe allergic reaction. **Stop injecting Kovaltry immediately and speak to your doctor at once if such reactions occur.** The following symptoms **could** be an early warning of these reactions:
- chest tightness/general feeling of being unwell
- dizziness

- feeling faint upon standing indicating a reduction in blood pressure
- feeling sick (nausea)

For children not previously treated with factor VIII medicines, **inhibitors** (see section 2) may form very commonly (more than 1 in 10 patients). For patients who have received previous treatment with factor VIII (more than 150 days of treatment) inhibitor antibodies (see section 2) may form uncommonly (less than 1 in 100 patients). If this happens **your medicine may stop working properly** and **you may experience persistent bleeding**. **If this happens, please contact your doctor immediately.**

Other possible side effects:

Common (may affect up to 1 in 10 users):
- stomach pain or discomfort
- indigestion
- fever
- local reactions where you injected the medicine (e.g. bleeding under the skin, intense itching, swelling, burning sensation, temporary redness)
- headache
- trouble sleeping
- hives
- rash/itchy rash

Uncommon (may affect up to 1 in 100 users):
- lymph nodes enlarged (swelling under the skin of the neck, armpit or groin)
- heart palpitations (feeling your heart beating hard, rapidly, or irregularly)
- rapid heartbeat
- dysgeusia (strange taste)
- flushing (redness of the face)

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

<table>
<tr><td colspan="2">To report any side effect(s):</td></tr>
<tr><td>Saudi Arabia:
The National Pharmacovigilance Centre (NPC).
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa</td><td>Oman:
Tel: +968 - 2444 1999
Fax: +968 - 24602287
Email: pharma-vigil@moh.gov.om
Website: www.moh.gov.om</td></tr>
<tr><td>United Arab Emirates (UAE):
Pharmacovigilance & Medical Device section
Tel: 80011111/+971 42301000
Email: pv@mohap.gov.ae
Website: www.mohap.gov.ae
P.O.Box 1853 Dubai</td><td>Kuwait:
Drug &Food Control, Ministry of Health ,Kuwait
Tel.: +965-24811532
Fax: +965-24811507
Email : Adr_reporting@moh.gov.kw
Website:
http://eservices.moh.gov.kw/SPCMS/DrugCmp.aspx</td></tr>
<tr><td colspan="2">Other Countries:
Please contact the relevant competent authority</td></tr>
</table>

5. How to store Kovaltry

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

Do not use this medicine after the expiry date which is stated on labels and cartons. The expiry date refers to the last day of that month.

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

This medicine may be stored at room temperature (up to 30 °C) for up to 6 months when you keep it in its outer carton. If you store it at room temperature it expires after 6 months or at the expiry date if this is earlier.
The new expiry date must be noted on the outer carton when the medicine is removed from the refrigerator.

Do not refrigerate the solution after reconstitution. The reconstituted solution must be used within 3 hours. This product is for single use only. Any unused solution must be discarded.

Do not use this medicine if you notice any particles in the solution or if the solution is cloudy.

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 Kovaltry contains

The **active** substance is octocog alfa (human coagulation factor VIII). Each vial of Kovaltry contains nominally 250, 500 or 1000 IU octocog alfa.
The **other** ingredients are sucrose, histidine, glycine (E 640), sodium chloride, calcium chloride dihydrate (E 509), polysorbate 80 (E 433), acetic acid glacial (E 260) and water for injections.

What Kovaltry looks like and contents of the pack

Kovaltry is provided as a powder and solvent for solution for injection. The powder is dry and white to slightly yellow . The solvent is a clear liquid.

Each single pack of Kovaltry contains
- a glass vial with powder
- a pre filled syringe with solvent
- a separate plunger rod
- a vial adapter
- a venipuncture set (for injection into a vein).

Kovaltry is available in pack sizes of:
- 1 single pack
- 1 multipack with 30 single packs

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bayer AG
Kaiser-Wilhelm-Allee 1
51368 Leverkusen, Germany.

Bulk Manufacturer:
Bayer HealthCare LLC
800 Dwight Way
Berkeley, CA 94710 USA

Secondary Packaging and Final Release
Bayer AG
51368 Leverkusen
Germany

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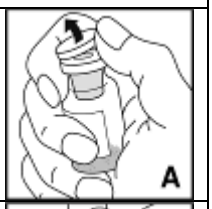
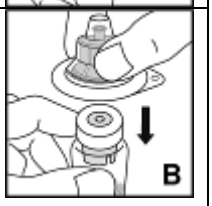
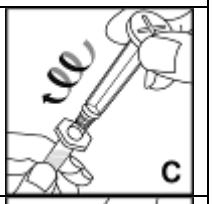
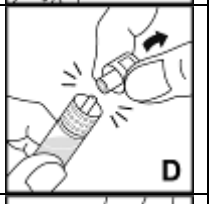
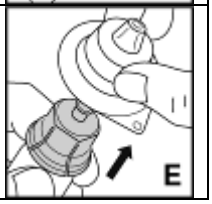
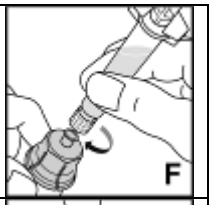
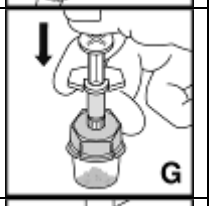
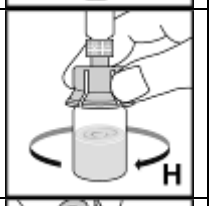
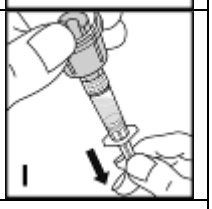
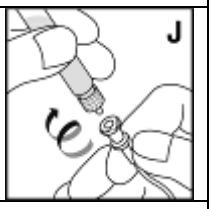
Detailed instructions for reconstitution and administration of Kovaltry

You will need alcohol swabs, gauze pads, plasters and tourniquet. These items are not included in the Kovaltry package.

1.	Wash your hands thoroughly using soap and warm water.	
2.	Hold an unopened vial and also a syringe in your hands to warm it to a comfortable temperature (do not exceed 37 °C).	
3.	Remove the protective cap from the vial **(A).**Wipe the rubber stopper on the vial with an alcohol swab and allow the stopper to air dry before use.	
4.	Place **the powder vial** on a firm, non slip surface. Peel off the paper cover on the plastic housing of the vial adapter. **Do not remove** the adapter from the plastic housing. Holding the adapter housing, place over the powder vial and firmly press down **(B)**. The adapter will snap over the vial cap. **Do not remove** the adapter housing at this point.	
5.	Hold the pre filled syringe with solvent upright. Grasp the plunger rod as per the picture and attach the rod by turning it firmly clockwise into the threaded stopper **(C)**.	
6.	Holding the syringe by the barrel, snap the syringe cap off the tip **(D)**. Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.	
7.	Now remove and discard the adapter housing **(E)**.	

8.	Attach the pre filled syringe to the threaded vial adapter by turning clockwise **(F).**	
9.	Inject the solvent by slowly pushing down on the plunger rod **(G)**.	
10.	Swirl vial gently until all the powder is dissolved **(H)**. Do not shake vial. Be sure that the powder is completely dissolved. Look to check there are no particles or discoloration before you use the solution. Do not use solutions containing visible particles or that are cloudy.	
11.	Hold the vial on the end above the vial adapter and syringe **(I)**. Fill the syringe by drawing the plunger out slowly and smoothly. Ensure that the full content of the vial is drawn into the syringe. Hold the syringe upright and push the plunger until no air is left in the syringe.	
12.	Apply a tourniquet to your arm.	
13.	Determine the point of injection and clean the skin with an alcohol swab.	
14.	Puncture the vein and secure the venipuncture set with a plaster.	
15.	Holding the vial adapter in place, remove the syringe from the vial adapter (the adapter should remain attached to the vial). Attach the syringe to the venipuncture set (**J**). Ensure that no blood enters the syringe.	
16.	Remove tourniquet.	
17.	Inject the solution into a vein over 2 to 5 minutes, keeping an eye on the position of the needle. The speed of injection should be based on your comfort, but should not be faster than 2 mL per minute.	
18.	If a further dose is needed, use a new syringe with the powder reconstituted as described above.	
19.	If no further dose is required, remove the venipuncture set and syringe. Hold a pad firmly over the injection site on your outstretched arm for about 2 minutes. Finally, apply a small pressure dressing to the injection site and consider if a plaster is necessary.	
20.	It is recommended that every time you use Kovaltry, you note down the name and the batch number of the product.	
21.	Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or physician how to throw away medicines you no longer use. These measures will help protect the environment	

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists