SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

PRODUCT NAME strength pharmaceutical form

KOVALTRY® 250 IU POWDER FOR INJECTION
KOVALTRY® 500 IU POWDER FOR INJECTION
KOVALTRY® 1000 IU POWDER FOR INJECTION
Recombinant antihaemophilic Factor VIII (octocog alfa).
Contains Sugar: Sucrose
ONE PREFILLED SYRINGE OF DILUENT FOR KOVALTRY® CONTAINS 2,5 mL OF STERILE WATER FOR INJECTION

Read all of this leaflet carefully before you start using KOVALTRY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- KOVALTRY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What KOVALTRY is and what it is used for

KOVALTRY is a medicine that 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 for the treatment and prevention (prophylaxis) of bleeding in patients with haemophilia A (congenital factor VIII deficiency). It is used by patients of all ages.

2. What you need to know before you use KOVALTRY

Do not use KOVALTRY:

- If you are allergic (hypersensitive) to octocog alfa, or to any of the other ingredients of KOVALTRY.
- If you have had allergic reactions to mouse or hamster protein.

Warnings and precautions

Tell your doctor or healthcare provider before taking KOVALTRY:

- If you are allergic to mouse or hamster protein.

Take special care:

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **KOVALTRY®** may cause undesirable effects. Please inform your doctor or pharmacist of any other medication you may be taking.

  If you experience tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing, you may be experiencing a rare severe sudden allergic reaction (a so-called anaphylactic reaction) to KOVALTRY. If this occurs, **stop administering the product** immediately and seek medical advice.

  Your doctor may carry out tests to ensure that your current dose of KOVALTRY provides adequate factor VIII levels.

- If your bleeding is not being controlled with your usual dose of KOVALTRY, consult your doctor immediately. You may have developed factor VIII inhibitors and your doctor may carry out tests to confirm this. Factor VIII inhibitors are antibodies in the blood which block the factor VIII you are using and makes it less effective to prevent and control bleeding.

- If you have previously developed a factor VIII inhibitor and you switch factor VIII products, you may be at risk of your inhibitor coming back.

If KOVALTRY is administered via central venous access devices (CVADs), catheter- related infections cannot be excluded. These are not associated to the product, but to the device.

Tell your doctor if you have been told you have heart disease or are at risk for heart disease.

Children and adolescents

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

Other medicines and KOVALTRY

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Interactions with other medicines are not known. However, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Including medicines obtained without a prescription.

Pregnancy and breastfeeding and fertility

Safe use during pregnancy and breast-feeding your baby has not been proven. Therefore, if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor, pharmacist or other health care provider for advice before using this product.

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 sucrose

Important information about some of the ingredients of KOVALTRY: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking KOVALTRY.

3. How to use KOVALTRY

Do not share medicines prescribed for you with any other person.

Always use KOVALTRY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

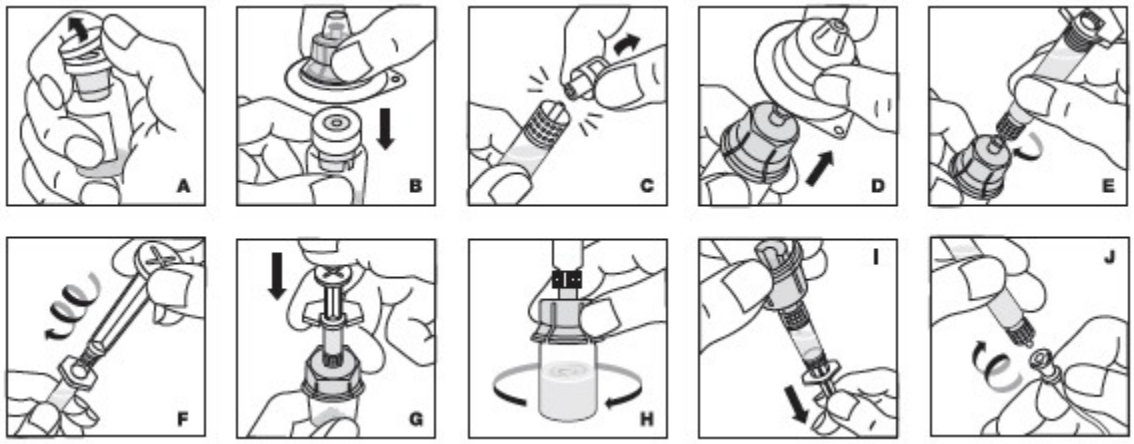
- **KOVALTRY is intended for intravenous administration only and must be administered within 3 hours after reconstitution (see below).**

You must use aseptic conditions (meaning clean and germ free) during reconstitution and administration. Use only the medical devices (vial adapter, pre-filled syringe containing solvent and venipuncture set) for reconstitution and administration that are provided with each package of KOVALTRY. If a package is opened or damaged, do not use this medical device.

- KOVALTRY must **not** be mixed with other infusion solutions. Follow the directions given by your doctor closely and use the instructions below as a guide:

Your doctor will tell you how long your treatment with KOVALTRY will last. Do not stop treatment early because … If you have the impression that the effect of KOVALTRY is too strong or too weak, tell your doctor or pharmacist.

Reconstitution and administration with vial adapter presentation



1. Wash your hands thoroughly using soap and warm water.
2. Warm both unopened vial and syringe in your hands to a comfortable temperature (do not exceed 37 °C).
3. Remove protective cap from the vial (A) then clean the rubber stopper with a sterile swab (or use an antiseptic spray).
4. Place product vial on a firm, non-skid surface. Peel off the paper cover on the vial adapter plastic housing. Do not remove the adapter from the plastic housing. Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. Do not remove the adapter housing at this step.
5. Holding the syringe by the barrel, snap the syringe cap off the tip (C). Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.
6. Now remove and discard the adapter housing (D).
7. Attach the pre-filled syringe to the threaded vial adapter by turning clockwise (E).
8. Hold the pre-filled sterile water for injection (SWFI) syringe upright, grasp the plunger rod per the diagram and attach the rod by turning it firmly clockwise into the threaded stopper (F).
9. Inject the diluent by slowly pushing down on the plunger rod (G).
10. Swirl vial gently until all material is dissolved (H). Do not shake vial. Be sure that the powder is completely dissolved. Do not use solutions containing visible particles or that are cloudy.
11. Hold the vial on end above the vial adapter and syringe (I). Fill the syringe by drawing the plunger out slowly and smoothly. Ensure that the entire content of the vial is drawn into the syringe. **Remove as much air as possible before removing the syringe from the vial by slowly and carefully pushing the air back into the vial**.
12. Apply a tourniquet.
13. Determine the point of injection and prepare antiseptically.
14. Puncture the vein and secure the venipuncture set with a plaster.
15. Holding the plunger in place, remove the syringe from the vial adapter (the latter should remain attached to the vial). Attach the syringe to the venipuncture set and ensure that no blood enters the syringe (J).
16. Remove tourniquet.
17. Inject the solution intravenously over several minutes, keeping an eye on the position of the needle. The speed of administration should be based on the patient's comfort but should not be faster than 2 mL/min maximum rate of infusion.

18. If a further dose needs to be administered, use a new syringe with product reconstituted as described above.
19. If no further dose is required, remove the venipuncture set and syringe. Hold a swab firmly over the injection site on the outstretched arm for approx. 2 minutes. Finally, apply a small pressure dressing to the wound.

Parenteral medicine should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Treatment of bleeding
How much KOVALTRY you should use and how often you should use it depends on many factors such as your weight, the severity of your haemophilia, where the bleed is and how serious it is, whether you have inhibitors and how high the inhibitor titre is and the factor VIII level that is needed.

Your doctor will calculate the dose of KOVALTRY and how frequently you should use it to get the necessary level of factor VIII activity in your blood. He/she should always adjust the amount of KOVALTRY to be administered and the frequency of administration according to your individual needs. Under certain circumstances larger amounts than those calculated may be required, especially for the initial dose.

Prevention of bleeding
If you are using KOVALTRY to prevent bleeding (prophylaxis), 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, given every 2 to 3 days. However, in some cases, especially for younger patients, shorter dose intervals or higher doses may be necessary.

Laboratory tests
It is strongly recommended that appropriate laboratory tests be performed on your plasma at suitable intervals to ensure that adequate factor VIII levels have been reached and are maintained.
For surgery in particular, including dental surgery, close monitoring of the replacement therapy by means of coagulation analysis must be carried out.

If bleeding is not controlled
If the factor VIII level in your plasma fails to reach expected levels, or if bleeding is not controlled after apparently adequate dose, you may have developed factor VIII inhibitors. This must be checked by an experienced doctor.
If you have the impression that the effect of KOVALTRY is too strong or too weak, talk to your doctor.

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 amount of KOVALTRY to control bleeding. If this dose does not control your bleeding your doctor may consider giving you an additional product, factor VIIa concentrate or (activated) prothrombin complex concentrate.
These treatments should be prescribed by doctors with experience in the care of patients with hemophilia A. Speak to your doctor if you would like further information on this.
Do not increase your dose of KOVALTRY you use to control your bleeding without consulting your doctor.

Speed of administration
KOVALTRY should be injected intravenously over several minutes. The rate of administration should be determined by the patient's comfort level.

Duration of treatment
Your doctor will tell you, how often and at what intervals KOVALTRY is to be administered.

Usually, the replacement therapy with KOVALTRY is a life-time treatment.

If you use more KOVALTRY than you should
If you have used more KOVALTRY than you should, please inform your doctor.

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

If you stop taking KOVALTRY
Do not stop using KOVALTRY without consulting your doctor.

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

4. Possible side effects

KOVALTRY can have side effects.

Not all side-effects reported for KOVALTRY are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects:

- stomach pain
- stomach discomfort
- indigestion
- fever
- local reactions where you injected the medication
- headache
- dizziness
- trouble falling asleep
- hives

- inhibitor (antibodies) may form. Factor VIII inhibitors are antibodies in the blood which may stop the factor VIII you are using from working properly. Consult your healthcare provider to make sure your child is carefully monitored with blood tests for the development of factor VIII inhibitors.

Less frequent side effects:

- hypersensitivity reactions including severe sudden allergic reaction (anaphylactic shock, e.g. tightness of the chest/general feeling of being unwell, dizziness and nausea and mildly reduced blood pressure, which may make you feel faint upon standing)
- dysgeusia (odd taste)
- lymph nodes enlarged
- heart palpitations
- rapid heartbeat
- chest discomfort
- rash/itchy rash
- flushing (redness of the face)
- inhibitor antibodies

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of KOVALTRY.

5. How to store KOVALTRY

Do not freeze. Store at or between 2 °C to 8 °C (in a refrigerator).
Keep the vial and the pre-filled syringe in the outer carton in order to protect from light.
You may store the product when kept in its outer carton at ambient room temperature (up to 25°C) for a single period of up to 12 months or up to 6 months at a temperature up to 30°C.
If the product is stored outside the refrigerator, please add the date removed from refrigeration and note a new expiry date on the carton and vial. The new expiry date should be 12 months (25°C) or 6 months (30°C) from the date product is removed from the refrigerator, or the previously stamped expiry date, whichever is earlier. Once the product is removed from refrigeration, it cannot be returned to the refrigerator.

The reconstituted solution should not have visible particulate matter and must be used immediately. If not, store at room temperature for no longer than 3 hours. This product is for single use only. Any unused solution must be discarded.
Do not use KOVALTRY after the expiry date which is stated on labels and cartons.
Do not use KOVALTRY if you notice any particles or the solution is not clear.
Store all medicines out of the reach of children. Do not store in bathrooms.
Return unused or expired medicines to your pharmacist/doctor for safe disposal.
Do not remove from the original packaging until administered.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KOVALTRY contains

Powder
The active substance is human coagulation factor VIII (octocog alfa). Each vial of KOVALTRY contains: 250 IU, 500 IU or 1000 IU octocog alfa.
The other ingredients are sucrose, histidine, glycine, sodium chloride, calcium chloride, polysorbate 80.
The active substance is human coagulation factor VIII (octocog alfa) produced by recombinant DNA technology.

Solvent
Water for injections, sterilised.

What KOVALTRY looks like and contents of the pack

KOVALTRY is a dry white to slightly yellow powder or cake in a clear glass vial and grey rubber blend stopper, plus lacquered aluminium seal with plastic flip-off top reconstitution cap. After reconstitution the solution is clear and should not have visible particulate matter. Medical devices for reconstitution and administration are provided with each package of KOVALTRY. Each pack of KOVALTRY contained in a cardboard carton is a vial and a pre-filled syringe with a separate plunger rod, and a venipuncture set (for injection into a vein).

Holder of Certificate of Registration

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Registration number: 1968/011192/07

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