An overview of information about KOVALTRY®

What is Kovaltry?

Kovaltry (Antihemophilic Factor [Recombinant]) is a clotting Factor VIII that is very similar to the Factor VIII that occurs naturally in human blood.

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What is Kovaltry used for?

Kovaltry is used for the treatment and prevention (prophylaxis) of bleeding in people with hemophilia A. It is also used for prophylaxis treatment of children with hemophilia A to reduce the occurrence of spontaneous bleeding episodes.

General dosing information

Treatment of bleeding

A doctor will calculate how much Kovaltry to use and how frequently it should be used to get the necessary level of Factor VIII activity in the blood.

Prevention of bleeding (prophylaxis)

For an adult or adolescent (>12 years of age), the usual dose for prevention of bleeding is **20–40 IU** of Kovaltry for every kilogram of body weight, given **2–3 x weekly**. In some cases, especially for younger patients, shorter dose intervals or higher doses may be necessary.

For children (≤12 years of age), the recommended dose for routine prophylaxis is **20–50 IU** of Kovaltry for every kilogram of body weight, given **2 x weekly**, **3 x weekly** or **every other day** according to individual requirements.

Administering Kovaltry

Kovaltry should be administered intravenously (into the vein) within 3 hours after reconstitution. Always use clean and germ-free (aseptic) conditions during reconstitution and administration.

Use only the medical devices (prefilled syringe containing diluent and administration set) for reconstitution and administration that are provided with each carton of Kovaltry. If a device package is opened or damaged, do not use this medical device.

Do **not** mix Kovaltry with other infusion solutions. Follow the directions given by a doctor on how to administer Kovaltry.

Before administration, visually inspect the medication for particles and discolouration.

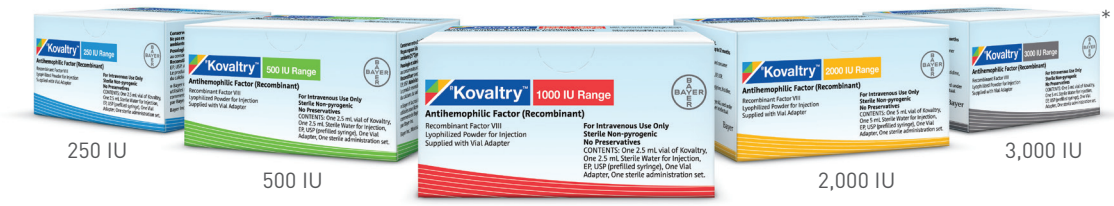
IU=international units.
* Canadian packaging may appear different.

Kovaltry®
Antihemophilic Factor (Recombinant)

Available vial sizes for Kovaltry

Kovaltry is a powder that must be reconstituted before administration. Kovaltry comes in vial sizes of 250, 500, 1,000, 2,000 and 3,000 IU.

Each carton contains a single-use vial with powder and a prefilled syringe containing sterile water for injection (diluent). A sterile administration set with a vial adapter is also provided.



250 IU | 500 IU | 1,000 IU | 2,000 IU | 3,000 IU

Storage instructions

Store Kovaltry in a refrigerator (2°C to 8°C). **Do not** freeze. Keep the vial and the prefilled syringe in the outer carton in order to protect them from light.

Kovaltry, when kept in its outer carton, may be stored at room temperature (up to 25°C) for a single period of up to 12 months. Do not return to the refrigerator once removed.

Kovaltry is for single use only, and any unused solution must be discarded.

Do not use after the expiry date stated on the labels and cartons or if you notice any particles or the solution is cloudy. Keep Kovaltry out of reach and sight of children.

Important safety information

Possible side effects (may affect more than 1% of people and less than 10%) that can occur when taking Kovaltry include stomach pain, stomach discomfort, indigestion, fever, local reactions where you injected the medication, headache, dizziness, trouble falling asleep, hives, itchy skin and rash.

A **lack of effect** (your medication not working) is a possible and serious side effect associated with Kovaltry. Contact your healthcare professional if this happens. **Hypersensitivity reactions**, including a severe sudden allergic (anaphylactic) reaction, are an uncommon serious side effect. Symptoms of this anaphylactic shock include tightness in the chest or a general feeling of being unwell, hives, dizziness and nausea, and feeling faint upon standing. If you experience these reactions, **stop taking Kovaltry** and **seek immediate medical attention**.

These are not all the possible side effects you may feel when taking Kovaltry. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

The development of circulating neutralizing antibodies to Factor VIII may occur during the treatment of patients with hemophilia A.

* Canadian packaging may appear different.

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