Kovaltry

(antihemophilic factor VIII [recombinant])

New Product Slideshow

MPR

Introduction

- **Brand name:** Kovaltry
- **Generic name:** Antihemophilic Factor VIII (recombinant)
- **Pharmacological class:** Clotting factor
- **Strength and Formulation:** 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU; lyophilized pwd for IV infusion after reconstitution; preservative-free
- **Manufacturer:** Bayer
- **How supplied:** Kit—1 (vial w. diluent and adapter)
- **Legal Classification:** Rx

KOVALTRY


BAYER
NDC 0026-3821-25
Kovaltry®
250 IU Range
BAYER
Antihemophilic Factor (Recombinant)
Recombinant Factor VIII
with Vial Adapter
For Intravenous Use Only.
Needleless
Reconstitution
Set

Indications

- **In patients with Hemophilia A**: to treat and control bleeding episodes, for perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes

Dosage & Administration

- Dosage Required (IU) = Body Weight (kg) × Desired % Factor VIII Increase × 0.5
- Individualize; infuse over 1–15mins if tolerated
- **Bleeding**:
  - **Minor**: obtain 20–40% FVIII increase; may repeat every 12–24hrs for ≥1 day until resolved or healing achieved
  - **Moderate**: obtain 30–60% FVIII increase; may repeat every 12–24hrs for 3–4 days until pain and acute disability resolved
  - **Major**: obtain 60–100% FVIII increase; may repeat every 8–24hrs until resolved

Dosage & Administration

- **Perioperative**:
  - **Minor** (pre- and post-op): obtain 30–60% FVIII increase; may repeat every 24hrs for ≥1 day until healed
  - **Major** (pre- and post-op): obtain 80–100% FVIII increase; may repeat every 8–24hrs until adequately healed, then continue for ≥7 days to maintain Factor VIII activity of 30–60%
- **Routine prophylaxis**:
  - **>12yrs**: 20–40 IU/kg 2–3 times weekly
  - **≤12yrs**: 25–50 IU/kg 2–3 times weekly or every other day according to requirements

Considerations for Special Populations

- **Pregnancy:** Give only if clearly needed
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** Consider higher or more frequent dosing in children to account for difference in clearance
- **Geriatric:** No overall differences in safety and efficacy

Contraindications

- Mouse or hamster protein sensitivity

Warnings/Precautions

- **Confirm** Factor VIII deficiency prior to treatment
- **Monitor** for development of Factor VIII inhibitors
- **Discontinue** if hypersensitivity reactions occur
- Cardiovascular disease or risk factors

Adverse Reactions

- Headache
- Pyrexia
- Pruritus
- Injection site reactions
- Rash
- Antibody formation
- Catheter-related infections

Mechanism of Action

- Kovaltry temporarily replaces the missing clotting Factor VIII that is needed for effective hemostasis

Clinical Trials

- The safety and efficacy of Kovaltry was evaluated in 3 international (including U.S.) clinical studies which included immunocompetent subjects with severe hemophilia A (Factor VIII activity ≤1%) and no history of Factor VIII inhibitors

Clinical Trials

- A total of 204 patients were enrolled in the completed clinical trials, of which 153 patients were ≥12 years of age and 51 patients were <12 years of age
- 140 patients were treated for ≥12 months
  - 43 of these were treated for 24 months

Clinical Trials

- **Study 1** was a multi-center, open-label, cross-over, uncontrolled, study in adolescents and adults (age ≥12 years to <65 years) that evaluated the pharmacokinetics, efficacy and safety of routine prophylaxis, and perioperative management of bleeding of Kovaltry

- The primary efficacy variable was annualized bleeding rate (ABR)

Clinical Trials

- **Study 2** was a multi-center, open-label, cross-over, uncontrolled, randomized study in adolescents and adults (age ≥12 years to <65 years) that evaluated the superiority of prophylaxis vs. on-demand treatment with Kovaltry over a one-year treatment period

- Primary efficacy variable was ABR

Clinical Trials

- **Study 3** was a multi-center, open-label, uncontrolled pediatric (age ≤12 years) study that evaluated the pharmacokinetics, efficacy and safety of routine prophylaxis, and perioperative management of bleeding of Kovaltry

- The primary efficacy variable was annualized number of total bleeds during routine prophylaxis that occurred within 48hrs following previous prophylaxis infusion

Clinical Trials

- Response to treatment of bleeds assessed as "Excellent" or "Good"
  - **Study 1**: Prophylaxis main study (80.9%); Prophylaxis extension (71.8%)
  - **Study 2**: Prophylaxis (61.6%); On-demand (69.7%)
  - **Study 3**: Previously treated patients (PTPs) 0–<6 years (97.8%); 6–12 years (81.0%); 0–12 years (90.1%)

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/kovaltry/drug/34585/