Idelvion

(coagulation factor IX [recombinant], albumin fusion protein)

New Product Slideshow

MPR

Introduction

- **Brand name:** Idelvion
- **Generic name:** Coagulation factor IX (recombinant), albumin fusion protein
- **Pharmacological class:** Clotting factor
- **Strength and Formulation:** 250 IU, 500 IU, 1000 IU, 2000 IU; per vial; lyophilized powder for IV inj after reconstitution; preservative-free
- **Manufacturer:** CSL Behring
- **How supplied:** Kit—1 (single-use vial + diluent, supplies)
- **Legal Classification:** Rx

IDELVION


1000
IDELVION®
Coagulation Factor IX
(Recombinant),
Albumin Fusion Protein
For Intravenous Administration
℞ only
CSL Behring

Indications

- In patients with **Hemophilia B:** to control and prevent bleeding episodes, for perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- **Limitations of use:** not for immune tolerance induction

Dosage & Administration

- **Dose (IU)** = body weight (kg) x desired FIX increase (% of normal or IU/dL) x reciprocal of recovery (IU/dL per IU/kg)
- Dose adjustment may be necessary in children <12yrs
- Individualize
- **Max infusion rate:** 10mL/min

Dosage & Administration

- Bleeding:
  - **Minor/Moderate:** 30–60% required; repeat every 48–72hrs for ≥1 day until bleeding stops and healing is achieved
  - **Major:** 60–100% required; repeat every 48–72hrs for 7–14 days until bleeding stops and healing is achieved; give maintenance dose weekly

Dosage & Administration

- Perioperative:
  - **Minor:** 50–80% required; repeat every 48–72hrs for ≥1 day or until healing is achieved
  - **Major:** initially 60–100% required; every 48–72hrs for 7–14 days or until bleeding stops and healing is achieved; may repeat every 48–72hrs for the first week or until healing is achieved; give maintenance dose 1–2 times weekly
- Routine prophylaxis:
  - **≥12yrs:** 25–40 IU/kg every 7 days or if well-controlled, may give 50–75 IU/kg every 14 days
  - **<12yrs:** 40–55 IU/kg every 7 days

Considerations for Special Populations

- **Pregnancy:** Give only if clearly needed
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** See Dosage & Administration
- **Geriatric:** Did not include subjects >65 years

Contraindications

- Hamster protein sensitivity

Warnings/Precautions

- **Discontinue** and treat if hypersensitivity symptoms occur
- **Monitor** for development of Factor IX inhibitors
- Liver disease, fibrinolysis, perioperative status, risk factors for thromboembolic events or disseminated intravascular coagulation; monitor for thromboembolism and consumptive coagulopathy

Adverse Reactions

- Headache
- Dizziness
- Hypersensitivity
- Rash
- Eczema

Mechanism of Action

- Idelvion is a recombinant protein that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis
- It is comprised of genetically fused recombinant coagulation Factor IX and recombinant albumin
- Fusion with recombinant albumin extends the half-life of Factor IX

Clinical Trials

- The safety and efficacy of Idelvion were evaluated in a prospective, open-label, multicenter clinical study (n=63) of previously treated male patients with hemophilia B who received at least 1 infusion of Idelvion as part of:
  - On-demand treatment of bleeding episodes
  - Peri-op management of major and minor surgical, dental, or other invasive procedures,
  - Routine prophylaxis once every 7-, 10- or 15-day intervals, or
  - Pharmacokinetic evaluation

Clinical Trials

- A total of 358 bleeding events were treated with Idelvion:
  - 57% (n=204) of events were spontaneous
  - 39% (n=140) of events were traumatic
  - 4% (n=14) of events were unknown
- Overall treatment efficacy was assessed for each bleeding episode based on a 4-point scale of excellent, good, moderate, or poor/no response

Clinical Trials

- **1 injection** was used to treat 94% (n=335) of bleeding episodes
- **2 injections** were used to treat 5% (n=18) of bleeding episodes
- **3 injections** were used to treat 1.4% (n=5) of episodes
- Of the total bleeding episodes:
  - 94% (n=337) were assessed as **Excellent or Good**
  - 2.5% (n=9) were assessed as **Moderate**
  - 0.3% (n= 1) were assessed as **Poor/no response**

Clinical Trials

- In 3 clinical studies, 13 patients received Idelvion for peri-op management of 15 surgical procedures
- Of the total surgeries, 11 were assessed as **Excellent** and 1 was assessed as **Good**
  - 3 minor surgeries were not rated

Clinical Trials

- Based on an analysis of 19 patients treated with Idelvion for on-demand therapy and weekly prophylaxis, the median annualized spontaneous bleeding rate (AsBr) during prophylaxis treatment was 0 vs. 45.4 during on-demand treatment
- Prophylaxis with Idelvion led to a **96% reduction** in the AsBR and an **89% reduction** in the annualized bleeding rate

- For more clinical data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/idelvion/drug/34593/