Hemlibra (emicizumab-kxwh)

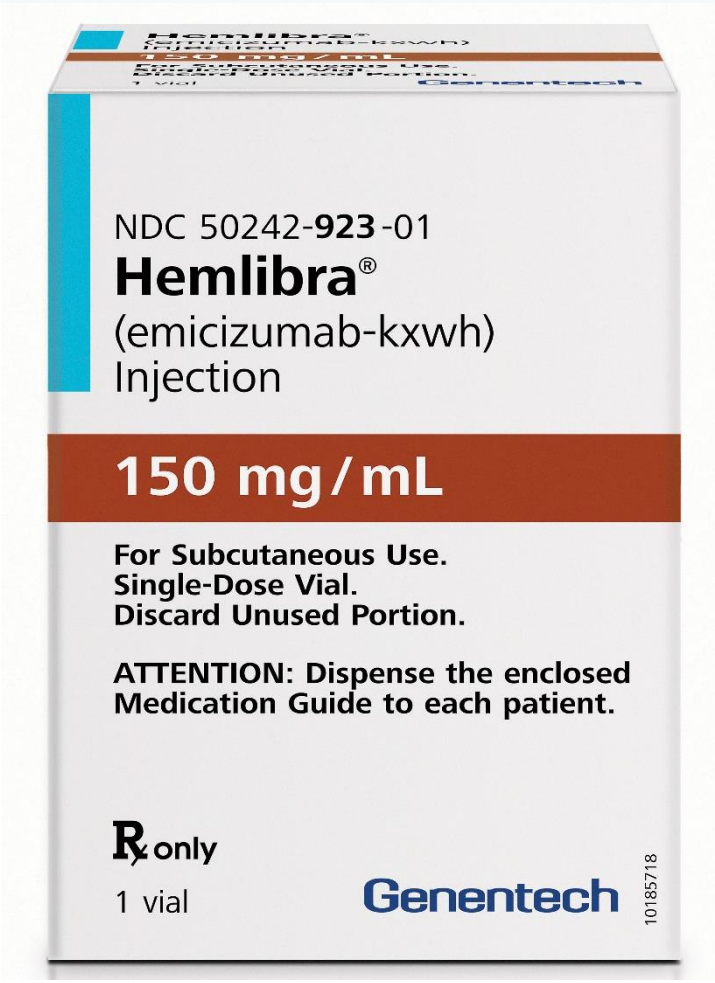
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Hemlibra
- **Generic name:** Emicizumab-kxwh
- **Pharmacological class:** Bispecific factor IXa- and factor X-directed antibody
- **Strength and Formulation:** 30mg/mL, 60mg/0.4mL, 105mg/0.7mL, 150mg/mL; per vial; soln for SC injection; preservative-free
- **Manufacturer:** Genentech
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

Hemlibra


NDC 50242-923-01
Hemlibra®
(emicizumab-kxwh)
Injection
150 mg/mL
For Subcutaneous Use.
Single-Dose Vial.
Discard Unused Portion.
ATTENTION: Dispense the enclosed
Medication Guide to each patient.
℞ only
1 vial
Genentech
10185718

Indications

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with **hemophilia A** with factor VIII inhibitors

Dosage & Administration

- **Do not** inject into moles, scars, tender skin, bruised, red, hard or not intact skin areas
- Give by SC inj into upper outer arms, thighs, or any abdomen quadrant; rotate inj sites
- Adults and children:
  - 3mg/kg once weekly for first 4 weeks, then 1.5mg/kg once weekly

Considerations for Special Populations

- **Pregnancy:** Insufficient data to adequately assess risk
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed child
- **Elderly:** Insufficient number of patients studied

Warnings/Precautions

- Thrombotic microangiopathy and thromboembolism can occur when average cumulative of >100U/kg per 24hrs of activated prothrombin complex concentrate (aPCC) was given for ≥24hrs
- Females of reproductive potential should use effective contraception during treatment

Interactions

- Risk of **thrombotic microangiopathy** and **thromboembolism** with concomitant aPCC; monitor and immediately discontinue if occurs
- May interfere with coagulation lab tests (eg, ACT, aPTT, aPTT-based assays, Bethesda assays [clotting-based] for FVIII inhibitor titers)
- Possible **hypercoagulability** with concomitant recombinant FVIIa or FVIII

Adverse Reactions

- Injection site reactions
- Headache
- Arthralgia
- Pyrexia
- Diarrhea
- Myalgia
- Thrombotic microangiopathy
- Thromboembolism

Mechanism of Action

- Hemlibra bridges activated factor IX and factor X to restore function of missing activated factor VIII that is needed for effective homeostasis

Clinical Studies

- The efficacy of Hemlibra for routine prophylaxis in hemophilia A patients with FVIII inhibitors was evaluated in **HAVEN 1** and **HAVEN 2** trials

Clinical Studies

- **HAVEN 1** (N=109) was a randomized, multicenter, open-label, clinical trial of adult and adolescent males aged 12–75 years with hemophilia A with FVIII inhibitors who previously received either on-demand or prophylactic treatment with bypassing agents

Clinical Studies

- For treated bleeds, the **annualized bleeding rate (ABR)** was 2.9 in the Hemlibra prophylaxis group vs 23.3 in the no prophylaxis group (87% reduction, 95% CI: 72.3%, 94.3%; *P*<0.0001)
  - 62.9% of Hemlibra patients had no bleeds vs 5.6% in the no prophylaxis group

Clinical Studies

- For all bleeds, the **ABR** was 5.5 in the Hemlibra prophylaxis group vs 28.3 in the no prophylaxis group (80% reduction, 95% CI: 62.5%, 89.8%; *P*<0.0001)
  - 37.1% of Hemlibra patients had no bleeds vs 5.6% in the no prophylaxis group

Clinical Studies

- In an intra-patient analysis, Hemlibra prophylaxis led to a statistically significant **79% reduction** (*P*=0.0003) in bleed rate for treated bleeds vs previous bypassing agent prophylaxis (ABR 3.3 vs 15.7, respectively)

Clinical Studies

- **HAVEN 2** was a single-arm, multicenter, open-label, clinical study in pediatric males aged <12 years or 12–17 years weighing <40kg with hemophilia A with FVIII inhibitors
  - Interim analysis evaluated efficacy in 23 patients who were aged <12 years

Clinical Studies

- Efficacy of weekly Hemlibra prophylaxis was compared with previous on-demand and prophylactic bypassing agent treatment
  - Median observation time for patients was 38.1 weeks

Clinical Studies

- For treated bleeds, the **ABR** was 0.2 with 87% experiencing no bleeds
- For all bleeds, the **ABR** was 2.9 with 34.8% experiencing no bleeds

- For more information, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/hemlibra/drug/34771/