Hemlibra

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Antihemorrhagic injection	None

PREPARATION and ADMINISTRATION

Hemlibra is a recombinant product that does not contain human plasma therefore blood consent is not required.

Hemlibra solution is a sterile, preservative-free, and ready to use solution that does not need to be diluted.

A syringe, a transfer needle with 5 micron filter and an injection needle are needed to withdraw solution from the vial and inject it subcutaneously.

Vials can be combined to reach the appropriate dose.

Solution should be inspected visually to ensure there is no particulate matter prior to administration.

SubCutaneous Injection Only

The injection should be restricted to the recommended injection sites: **the abdomen, the upper outer arms and the thighs**

Alternating the site of injection may help prevent or reduce injection site reactions and during treatment, other medicinal products for subcutaneous administration should, preferably, be injected at different anatomical sites.

Requirements and Monitoring

Serious thrombotic adverse reactions have been reported when on average a cumulative amount of >100 Unit/kg/24 hours of Feiba NF (activated prothrombin complex concentrate [aPCC]) was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. Discontinue Feiba at least 24 hours before starting Hemlibra and avoid use of aPCC during Hemlibra treatment unless no other treatment options/alternatives are available.

Accidental overdose may result in hypercoagulability. Patients who receive an accidental overdose should immediately contact their physician and be monitored closely.

Baseline vitals before starting injection. Reassess 15 min after completion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Indicated for hemophilia A (congenital factor VIII deficiency) patients with or without factor VIII inhibitors for:

- Routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes.

ADVERSE EFFECTS

Injection site reactions (ISRs) were reported very commonly (21%) from clinical trials. All ISRs observed in the Hemlibra clinical trials were reported as being non-serious and mild to moderate in intensity and 95% resolved without treatment. The most commonly reported ISR symptoms were injection site erythema (11%), injection site pain (4%) and injection site

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pruritus (3%).

If an AE is suspected: Consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab.

DOSAGE

Adults –Ask patient if they have a Factor First card supplying the recommended treatment and dosage
Pediatrics – Consult Hematology clinic or Hematologist on call for dosing

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system.

COMPATIBILITY, STABILITY

- Single use vials. Do not use past expiry date
- Before injection, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- Ensure patient has not received an activated Prothrombin Complex Concentrate (aPCC) (e.g. Feiba) within in the past 24 hours to limit adverse events.

RECONSTITUTION

- Not required.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Hemlibra product monograph. Found at https://www.rochecanada.com/en/products/pharmaceuticals/product-information.html