Patient Card | Hemlibra® (Emicizumab)
Subcutaneous Injection

This Patient Card contains important safety information that you need to know before, during and after treatment with Hemlibra (emicizumab).

Patients/caregivers should carry this Patient Card at all times while on treatment and for 6 months after your last dose of Hemlibra. This is because the effects of Hemlibra can last for several months, so side effects can occur even when you are no longer being treated with Hemlibra. You can keep it in your wallet or purse.

Please present the card at visits to doctors, hospital clinics, laboratory professionals or pharmacists to provide information on emicizumab treatment and risks.

HK Ref: cRMP v4.0; ARMM Patient Card v4.0.1.0 HK 02/2024
Global Ref: cRMP v4.0; Singapore ARMM v4.0.1

IMPORTANT SAFETY INFORMATION

Tell your doctor that you are receiving Hemlibra for the treatment of Haemophilia A before going for laboratory tests that measure how well your blood is clotting. Your doctor may refer to these laboratory tests as “coagulation tests” and “inhibitor assays”. This is because the presence of Hemlibra in the blood may interfere with some of these laboratory tests, leading to inaccurate results.

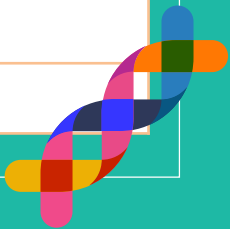
Before you start using Hemlibra, it is important you talk to your doctor about when and how to use “bypassing agents” while receiving Hemlibra. This is because serious and potentially life-threatening side effects have been observed when a “bypassing agent” called activated prothrombin complex concentrate (aPCC) was used in patients who were also receiving Hemlibra. These included:

- **Destruction of red blood cells / Thrombotic microangiopathy (TMA)** – this is a serious and potentially life-threatening condition where there is damage to the lining of blood vessels and formation of blood clots in small blood vessels. This can lead to damage in the kidney and/or other organs. Signs and/or symptoms of TMA include confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, stomach (abdomen) or back pain, nausea or vomiting, feeling sick and decreased urination.

- **Thromboembolism** – Blood clots may form and in rare cases blood clots may cause a life-threatening blockage of blood vessels. Signs and/or symptoms of thromboembolism include swelling in arms or legs, pain or redness in your arms or legs, shortness of breath, chest pain or tightness, fast heart rate, cough up blood, feel faint, headache, numbness in your face, eye pain or swelling and trouble seeing.

If you experience any of the above signs and/or symptoms during or after treatment with Hemlibra, CONTACT YOUR DOCTOR IMMEDIATELY.

My Name	
My Diagnosis	
Haemophilia Treatment Centre (HTC)	
HTC Telephone Number	
HTC Doctor	
Emergency Contact Person	
Telephone Number	



Notice to healthcare professionals reading this Patient Card:

Please be aware of the following information:

- Thrombotic microangiopathy and thromboembolism have been associated with Hemlibra and aPCC

- Guidance on the use of bypassing agents in patients receiving Hemlibra
  - Treatment with bypassing agents should be discontinued the day before starting Hemlibra therapy
  - Physicians should discuss with all patients and/or caregivers the exact dose and schedule of bypassing agents to use, if required while receiving Hemlibra prophylaxis

- Use of aPCC should be avoided unless no other treatment options/alternatives are available.

- Hemlibra affects the intrinsic pathway clotting-based laboratory tests including the activated clotting time (ACT), activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one-stage factor VIII activity (refer to Table 1 below).

Table 1 | Coagulation Test Results Affected and Unaffected by Hemlibra

Results *Affected* by Hemlibra	Results *Unaffected* by Hemlibra
• Activated partial thromboplastin time (aPTT) • Activated clotting time (ACT) • One-stage, aPTT-based, single-factor assays (eg. FVIII activity) • aPTT-based activated protein C resistance (APC-R) • Bethesda assays (clotting-based) for FVIII inhibitor titers	• Thrombin time (TT) • One-stage, prothrombin time (PT)-based, single-factor assays • Chromogenic-based single-factor assays other than FVIII • Immuno-based assays (e.g. ELISA, turbidometric methods) • Bethesda assays (bovine chromogenic) for FVIII inhibitor titers. • Genetic tests of coagulation factors (e.g. Factor V Leiden, Prothrombin 20210)

Contact the patient's haematologist for assistance in interpreting laboratory test results or for guidance on the use of bypassing agents in patients receiving Hemlibra prophylaxis.

What additional important information should I know?

Call for Reporting

- Roche monitors the benefits and safety risks of its medicines. This will allow quick identification of new safety information.
- Tell your doctor, nurse or pharmacist about any side effect you experience, bothers you or that does not go away. This includes any possible side effects not listed in the package leaflet.
- The side effects listed in this brochure are not all of the possible side effects that you could experience with Hemlibra.
- Talk to your doctor, nurse or pharmacist if you have any questions, problems or for more information.
- Please report any side effects to Roche Hong Kong Patient Safety Team by emailing hong_kong.drug_safety@roche.com. By reporting side effects, you can help provide more information on the safety of this medicine.
- For full information on all possible adverse events, please see the full prescribing information or the Patient Leaflet.