PATIENT CARD

If you would like this information in a digital format please ask your Haemophilia Treatment Centre about MedWALLET your digital medication passport.

HEMLIBRA®
emicizumab
subcutaneous injection

PATIENT CARD*
TO ENSURE SAFE USE OF HEMLIBRA FOR TREATMENT OF HAEMOPHILIA A

- These materials describe recommendations to minimise or prevent important risks of the drug.
- See the Hemlibra package leaflet for more information on possible side effects of Hemlibra.

PATIENTS/CARERS SHOULD CARRY THIS CARD AT ALL TIMES INCLUDING IN EMERGENCIES

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

IMPORTANT SAFETY INFORMATION

In case of an emergency,

- Contact an appropriate medical professional for immediate medical care.
- Should any questions related to your haemophilia A or current treatment arise, please have them contact your doctor.

Tell your doctor if you are using Hemlibra before you have laboratory tests that measure how well your blood is clotting. This is because the presence of Hemlibra in the blood may interfere with some of these laboratory tests, leading to inaccurate results.

Serious and potentially life-threatening side effects have been observed when a "bypassing agent" called aPCC (FEIBA) was used in patients who were also receiving Hemlibra. These included:

- 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 kidneys and/or other organs.
- Thromboembolism - blood clots may form and in rare cases these blood clots may cause a life-threatening blockage of blood vessels.

*This educational material is mandatory as a condition of the marketing authorisation of subcutaneous Hemlibra in the treatment of patients with haemophilia A in order to further minimise important selected risks.

PLEASE READ THIS INFORMATION CAREFULLY BEFORE ADMINISTERING THE PRODUCT

In case of an emergency:

- Contact an appropriate medical professional for immediate medical care.
- Should any questions related to your haemophilia A or current treatment arise, please have them contact your doctor:

Name

Tel/Fax

Email

[Your haematologist's contact information]

NOTICE TO HEALTHCARE PROFESSIONALS READING THIS CARD - PLEASE BE AWARE OF:

Thrombotic microangiopathy associated with Hemlibra and aPCC

- Cases of thrombotic microangiopathy (TMA) were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of >100U/kg/24 hours of activated prothrombin complex concentrate (aPCC) for 24 hours or more was administered.
- Patients receiving Hemlibra prophylaxis should be monitored for the development of TMA when administering aPCC.

Thromboembolism associated with Hemlibra and aPCC

- Thrombotic events (TE) were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of >100U/kg/24 hours of activated prothrombin complex concentrate (aPCC) for 24 hours or more was administered.
- Patients receiving Hemlibra prophylaxis should be monitored for the development of thromboembolism when administering aPCC.

Use of bypassing agents in patients receiving Hemlibra

- Treatment with prophylactic 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.
- Hemlibra increases patients' coagulation potential. The bypassing agent dose required may therefore be lower than that used without Hemlibra prophylaxis. The dose and duration of treatment with bypassing agents will depend on the location and extent of bleeding, and the patient's clinical condition.
- For all coagulation agents (aPCC, rFVIIa, FVIII, etc.), consideration should be given to verifying bleeds prior to repeated dosing.
- Use of aPCC should be avoided unless no other treatment options/alternatives are available.
  - If aPCC is the only option to treat bleeding for a patient receiving Hemlibra prophylaxis, the initial dose should not exceed 50 U/kg and laboratory monitoring is recommended (including but not restricted to renal monitoring, platelet testing, and evaluation of thrombosis).
  - If bleeding is not controlled with the initial dose of aPCC up to 50 U/kg, additional aPCC doses should be administered under medical guidance or supervision, and the total aPCC dose should not exceed 100 U/kg in 24 hours of treatment.
  - Treating physicians must carefully weigh the risk of TMA and TE against the risk of bleeding when considering aPCC treatment beyond 100U/kg in 24 hours.
- The safety and efficacy of emicizumab has not been formally evaluated in the surgical setting. If you require bypassing agents in the perioperative setting, it is recommended that the dosing guidance above for aPCC be followed by your doctor.
- In clinical trials, no cases of TMA or TE were observed with use of activated recombinant human FVII (rFVIIa) alone in patients receiving Hemlibra prophylaxis.; however, the lowest dose expected to achieve hemostasis should be prescribed. Due to the long half-life of Hemlibra, bypassing agent dosing guidance should be followed for at least 6 months following discontinuation of Hemlibra prophylaxis.
- Please refer to section 4.4 of the New Zealand Datasheet for additional information and comprehensive instructions.

Laboratory coagulation test interference

- Hemlibra affects assays for activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one stage Factor VIII activity.
- Therefore, aPTT based coagulation laboratory test results in patients who have been treated with Hemlibra prophylaxis should not be used to monitor Hemlibra activity, determine dosing for factor replacement or anti-coagulation, or measure Factor VIII inhibitors titres.
- However, single-factor assays utilising chromogenic or immuno-based methods are not affected by emicizumab and may be used to monitor coagulation parameters during treatment, with specific considerations for FVIII chromogenic activity assays.
- Chromogenic Factor VIII activity assays containing bovine coagulation factors are insensitive to

emicizumab (no activity measured) and can be used to monitor endogenous or infused Factor VIII activity, or to measure anti-FVIII inhibitors. A chromogenic Bethesda assay utilising a bovine-based Factor VIII chromogenic test that is insensitive to emicizumab may be used.

- Laboratory tests affected and unaffected by Hemlibra are shown in the list below:

Coagulation Test Results Affected and Unaffected | by Hemlibra

RESULTS AFFECTED BY HEMLIBRA

- Activated partial thromboplastin time (aPTT)
- Activated clotting time (ACT)
- One-stage, aPTT- based, single-factor assays
- aPTT- based Activated Protein C Resistance (APC-R)
- Bethesda assays (clotting based) for FVIII inhibitor titres

RESULTS UNAFFECTED BY HEMLIBRA

- Thrombin time (TT)
- One-stage, 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 titres
- Genetic tests of coagulation factors (e.g. Factor V Leiden, Prothrombin 20210)

Please refer to the datasheet for additional information (section 4.5)

Contact the patient's haematologist listed above 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

- 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.
- You can also report side effects directly to the Centre for Adverse Reactions Monitoring (CARM) at https://pophealth.my.site.com/carmreportnz/s/. By reporting side effects you can help provide more information on the safety of this medicine.
- Adverse reactions (side effects) should also be reported at MedInfo.roche.com or Roche Medical Information on 0800 276 243.
- For full information on all possible adverse events please see the New Zealand Data Sheet at www.medsafe.govt.nz.

Scan the QR code to go to Medsafe Data Sheet

Scan the
QR code to go to
www.hemlibra.co.nz

Scan the
QR code to go to
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COMPANY CONTACT POINT

Call
Roche Medical Information on 0800 276 243

Visit
www.Roche.co.nz

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