PATIENT/CARER GUIDE

HEMLIBRA®
emicizumab
subcutaneous injection

PATIENT/CARER GUIDE*

FOR PATIENTS 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, or the Consumer Medicine Information on the Medsafe website (www.medsafe.govt.nz), for more information on Hemlibra

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 having 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 activated prothrombin complex concentrate (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

What is Hemlibra?

Hemlibra, otherwise known as emicizumab, belongs to a group of medicines called "monoclonal antibodies".

It is a prescription medicine used to prevent bleeding or reduce the frequency of bleeding in people with haemophilia A with or without factor VIII inhibitors.

How has Hemlibra been studied in Haemophilia A?

Hemlibra has been studied in adults and children with haemophilia A.

How is Hemlibra used in Haemophilia A?

Hemlibra is injected under the skin (subcutaneously) and is present in the blood at stable levels when used as prescribed. Your doctor or nurse will show you and/or your carer how to inject Hemlibra. Once you and/or your caregiver have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.

This medicine is used to prevent bleeding or reduce the number of bleeding episodes in people with this condition. This medicine is not to be used to treat a bleeding episode.

If I am on Hemlibra, can I continue to use bypassing agents (such as NovoSeven or FEIBA) to prevent bleeding?

A patient on emicizumab can use bypassing agents (BPA) to treat breakthrough bleeds based on the guidance on the use of BPA provided in the prescribing information.

Before you start using Hemlibra, it is very important you talk to your doctor about when and how to use bypassing agents while receiving Hemlibra, as this may differ from before. Serious and potentially life-threatening side effects have been observed when aPCC (FEIBA) was used in patients who were also receiving Hemlibra.

WHAT DO I DO IF I DEVELOP A BREAKTHROUGH BLEED WHILE ON HEMLIBRA ?

When you think you may be having a breakthrough bleed

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

USING A BYPASSING AGENT WHILE RECEIVING HEMLIBRA

Before you start using Hemlibra, talk to your doctor and carefully follow their instructions regarding when to use a bypassing agent and the dose and schedule you should use.

- Treatment with prophylactic bypassing agents should be discontinued the day before starting Hemlibra therapy.
- Your doctor should discuss with you or your caregiver the exact dose and schedule of bypassing agents to use, if required while receiving Hemlibra.
- Hemlibra increases the ability of your blood to clot. The bypassing agent dose required may therefore be lower than that used before starting Hemlibra. The dose and duration of treatment with bypassing agents will depend on the location and extent of bleeding, and on your 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 with consideration made to laboratory monitoring and verification of bleeds prior to repeated dosing. 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 thromboembolism against the risk of bleeding when considering aPCC treatment beyond a maximum of 100 U/kg in 24-hours.
- The safety and efficacy of Hemlibra 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.

WHAT IMPORTANT INFORMATION SHOULD I ALWAYS TELL HEALTHCARE PROVIDERS TO HELP THEM TAKE CARE OF ME?

- Tell your doctor that you are receiving Hemlibra for the treatment of haemophilia A.
- 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, and lead to unreliable results. Your doctor may refer to these laboratory tests as 'coagulation tests' and 'inhibitor assays'.
- Hemlibra affects assays for activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one stage factor VIII activity (see Table 1 below).
- Therefore, aPTT and one-stage FVIII assay test results in patients who have been treated with Hemlibra prophylaxis should not be used to assess Hemlibra activity, determine dosing for factor replacement or anti coagulation, or measure factor VIII inhibitor titres (see below).
- 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 unaffected by Hemlibra are shown in Table 1 below.

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 – aPTT-based Activated Protein C Resistance (APC-R) – Bethesda assays (clotting-based) for FVIII inhibitor titres	– Thrombin time (TT) – One-stage, PT based, single factor assays – Chromogenic based single-factor assays other than FVIII[1] – 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)

WHAT IS THE PATIENT CARD?

The Patient card contains important safety information that you need to know before, during and after treatment with Hemlibra.

- Your doctor, pharmacist or nurse should give you a Hemlibra Patient Card prior to starting Hemlibra.
- Keep the Patient Card with you all the time - you can keep it in your wallet or purse.
- Show the Patient Card to anyone who is giving you medical care. This includes any doctor, pharmacist, lab personnel, nurse or dentist you see - not just the specialist who prescribes your Hemlibra.
- Tell your partner or caregiver about your treatment and show them the Patient Card because they may notice side effects that you are not aware of.
- Keep the Patient Card with you 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.

If you would like a digital version of the patient card, please speak to your Haemophilia Treatment Centre about MedWALLET a digital medication passport.

WHAT ADDITIONAL IMPORTANT INFORMATION SHOULD I KNOW?

CALL FOR REPORTING

- Tell your doctor, nurse or pharmacist about any side effect you experience, that 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 call Roche Medical Information on 0800 276 243.
- For full information on all possible side effects please see the Consumer Medicines Information on the Medsafe website (www.medsafe.govt.nz).

Hemlibra®(emicizumab), 30 mg in 1 mL, 60 mg in 0.4 mL, 105 mg in 0.7 mL and 150 mg in 1 mL ready-to-use solution for subcutaneous (SC) injection, is a **Prescription Medicine** used to prevent bleeding or reduce the frequency of bleeding in people with haemophilia A with or without factor VIII inhibitors

Ask your doctor if Hemlibra® is right for you.

HEMLIBRA is funded for patients with haemophilia A with and without inhibitors, who meet predefined criteria.

Use only as directed. If symptoms continue or you have side effects, see your healthcare professional. For more information about Hemlibra®:

- talk to your health professional; or
- visit medsafe.govt.nz for Hemlibra® Consumer Medicine Information; or
- visit roche.co.nz or call Roche on 0800 276 243.

Hemlibra® has risks and benefits.

Possible common side effects include: injection site reactions, headache, joint pains, high temperature or fever, diarrhoea, muscle aches, hives (urticaria), rash; swollen lips, mouth, face, tongue and/or throat and/or difficulty in swallowing and breathing (angioedema)

Do not use Hemlibra® if: you have had an allergic reaction to HEMLIBRA or any of the ingredients, or to any medicines that are made using Chinese hamster ovary cells.

Tell your doctor if: you have allergies to any other medicines, foods, preservatives or dyes; you are taking bypassing agents or any other blood product; you are pregnant or plan to become pregnant or are breastfeeding; you are using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following: confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, abdominal or back pain, feeling sick (nausea), being sick (vomiting) or urinating less – may be signs of thrombotic microangiopathy (TMA); swelling, warmth, pain or redness – may be signs of a blood clot in a vein near the surface of the skin; headache, numbness in your face, eye pain or swelling or vision impairment – may be signs of a blood clot in a vein behind your eye; blackening of the skin – may be a sign of severe damage to the skin tissue; loss of consciousness; if it appears that HEMLIBRA is no longer working for you – an uncommon occurrence of antibody production against HEMLIBRA.

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COMPANY CONTACT POINT

Call

Roche Medical Information on 0800 276 243

Visit

www.Roche.co.nz

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

Scan the QR code to go to Medsafe CMI

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