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 for more information on possible side effects of Hemlibra

Please read this information carefully before administering the product.

IMPORTANT SAFETY INFORMATION

- Serious and potentially life-threatening side effects have been observed when a "bypassing agent" called activated prothrombin complex (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 kidneys and/or other organs.
    - **Thromboembolism** - Blood clots may form and in rare cases these blood clots may cause a life-threating blockage of blood vessels.
- Stop using Hemlibra and aPCC and talk to your treating physician immediately if you or your caregiver notice any of the following side effects:
    - Confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, stomach (abdominal) or back pain, nausea or vomiting, feeling sick, decreased urination. These may be signs and symptoms of TMA.
    - 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, trouble seeing. These may be signs and symptoms of thromboembolism.
- 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.
- In case of an emergency,
    - Contact an appropriate medical professional for immediate medical care.
    - Should any questions related to your condition or current treatment arise, please have them contact your doctor.

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.

What you should know about Hemlibra

What is Hemlibra?

Hemlibra, otherwise known as emicizumab, belongs to a group of medicines called “monoclonal antibodies”, which are a type of protein that recognise and bind to a target in the body.

Hemlibra is used to treat people with Haemophilia A. Haemophilia A is an inherited bleeding condition caused by the lack of factor VIII, an essential substance required for blood to clot and stop any bleeding. This medicine is used to prevent bleeding or to reduce the number of bleeding episodes in people with Haemophilia A. It is not to be used to treat a bleeding episode.

Hemlibra can be used in all age groups.

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). Your doctor or nurse will show you and/or your caregiver 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.

If I am on Hemlibra, can I continue to use bypassing agents to prevent bleeding?

A patient on emicizumab can use “bypassing agents” (medicines that help blood to clot but work in a different way from factor VIII) to treat breakthrough bleeds based on the guidance on the use of bypassing agents 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. Examples of bypassing agents include activated prothrombin complex (aPCC) and recombinant factor VIIa.

What are the possible serious side effects of using aPCC while receiving Hemlibra?

Serious and potentially life threatening side effects have been observed when 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 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.

Stop using Hemlibra and aPCC and talk to your treating physician immediately if you or your caregiver notice any of the following side effects:

- Confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, stomach (abdominal) or back pain, nausea or vomiting, feeling sick decreased urination. These may be signs and symptoms of TMA.

- 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, trouble seeing. These may be signs and symptoms of thromboembolism.

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 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.
- Please talk to your treating physician before self-administering any treatment for a bleed.
- Use aPCC only if no other treatment can be used.

What additional important information should I know?

Call for Reporting

- Roche monitors benefits and safety risks of its medicines. This will allow quick identification of new safety information.
- Tell your doctor, pharmacist or nurse about any side effect you experience, bothers you or that does not go away, including those not listed in this guide. The side effects listed in this guide are not all of the possible side effects that you could experience with Hemlibra.
- Talk to your doctor, pharmacist or nurse if you have any questions, problems or for more information.
- Please report any side effects to Roche Hong Kong Pharmacovigilance Partners by emailing to **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.