FOR USE IN MALTA

Hemlibra (emicizumab):
Patient/Carer Guide

Important Risk Minimisation Information for Patients

Please read this material along with the Package Leaflet supplied with this medicines or also available on www.ema.europa.eu before taking this medicine

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This educational material is mandatory as a condition of the marketing authorisation, to ensure the safe and effective use of the product and appropriate management of the important selected risks.

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- Risk minimisation materials for Hemlibra (emicizumab) are assessed and approved by the Malta Medicines Authority.
- 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.

Important Safety Information

- Serious and potentially life-threatening side effects have been observed when a “bypassing agent” called 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.
  - **Blood clots (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:

- Destruction of red blood cells (thrombotic microangiopathy):
  - confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, vague belly (abdominal) or back pain, feeling sick (nausea), being sick (vomiting) or urinating less – these symptoms may be signs of thrombotic microangiopathy.

- Blood clots (thromboembolism):
  - swelling, warmth, pain or redness – these symptoms 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 problems with your vision – these symptoms may be signs of a blood clot in a vein behind your eye.
  - blackening of the skin – this symptom may be a sign of severe damage to the skin tissue.
- Tell your doctor if you are using Hemlibra before you have laboratory tests that measure how well your blood is clotting. This is because of 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 haemophilia A or current treatment arise, please have them contact your doctor.

Please read this information carefully before administering the product.

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What you should know about Hemlibra

What is Hemlibra?

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

Hemlibra is a medicine used for treating patients of all ages with haemophilia A (congenital factor VIII deficiency):

- who have developed factor VIII inhibitors
- who have not developed factor VIII inhibitors with:
  - severe disease (the factor VIII blood level is less than 1%)
  - moderate disease (the factor VIII blood level is from 1% to 5%) with severe bleeding phenotype.

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 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.

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 to prevent bleeding?

A patient on emicizumab can use “bypassing agents” (medicines that help blood clot but which work in a different way from factor VIII) to treat break-through bleeds based on the guidance on the use of bypassing agents provided in the prescribing information. Examples of bypassing agents include activated prothrombin complex concentrate (aPCC) and recombinant FVIIa (rFVIIa).

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 was used in patients who were also receiving Hemlibra.

Serious side effects of using aPCC while receiving Hemlibra

- Serious and potentially life-threatening side effects have been observed when a “bypassing agent” called 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.
  - **Blood clots (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:

- Destruction of red blood cells (thrombotic microangiopathy):
  - confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, vague belly (abdominal) or back pain, feeling sick (nausea), being sick (vomiting) or urinating less – these symptoms may be signs of thrombotic microangiopathy.
- Blood clots (thromboembolism):
  - swelling, warmth, pain or redness – these symptoms 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 problems with your vision – these symptoms may be signs of a blood clot in a vein behind your eye.
  - blackening of the skin – this symptom may be a sign of severe damage to the skin tissue.

What do I do if I develop a break-through bleed while on Hemlibra?

When you think you may be having a break-through 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.
- Please talk to your treating physician before self-administering any treatment for a bleed.

- Use aPCC only if no other treatment can be used.
  - If aPCC is required, talk to your treating physician in case you feel you need a total of more than 50 units/kg of aPCC.
  - Despite limited experience with concomitant administration of antifibrinolytics with aPCC or rFVIIa in patients treated with Hemlibra, you should know that there may be a possibility of thrombotic events using anti-fibrinolytics administered intravenously in combination with aPCC or rFVIIa.

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.”

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 additional important information should I know?

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre,
Roche Products (Ireland) Limited, 3030 Lake Drive,
Citywest Business Campus, Dublin 24, D24 KX6Y, Ireland.
Telephone: 00 353 (1) 469 0700;
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:
http://www.medicinesauthority.gov.mt/adrportal,
and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate,
Medicines Authority, Sir Temi Żammit Buildings,
Malta Life Sciences Park, San Ġwann SĠN 3000, Malta
Email: postlicensing.medicinesauthority@gov.mt

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns or for more information.

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