Patient/Carer Guide

Hemlibra®▼(emicizumab)

Subcutaneous injection for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors

This educational material is provided by Roche Products Limited and Chugai Pharma UK Ltd and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks

For more information on Hemlibra, please see the Patient Information Leaflet (PIL) that comes with your medicine

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get

Risk minimisation materials for Hemlibra (emicizumab) are assessed by the Medicines Authority. These materials describe recommendations to minimise or prevent important risks of the drug.

IMPORTANT SAFETY INFORMATION

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

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.

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) - 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.

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines, as some other medicines might be associated with an increased risk of thrombotic microangiopathy.

What you should know about Hemlibra

What is Hemlibra?

Hemlibra contains the active substance "emicizumab". This belongs to a group of medicines called "monoclonal antibodies". Monoclonal antibodies are a type of protein that recognise and bind to a target in the body. Hemlibra is used to treat people of all age groups.

What is it used for?

Hemlibra is a medicine used for treating patients of all ages with haemophilia A who have developed factor VIII inhibitors.

The medicine prevents bleeding or reduces bleeding episodes in people with this condition. Haemophilia A is an inherited condition caused by a lack of factor VIII, an essential substance required for blood to clot and stop any bleeding.

How is Hemlibra used?

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 recombinant factor VII (rFVIIa) or activated prothrombin complex concentrate (aPCC), to prevent bleeding?

Treatment with prophylactic bypassing agents should be discontinued the day before starting Hemlibra therapy.

Before you start using Hemlibra, it is very important to talk to your doctor about using "bypassing agents" (medicines that help blood clot but which work in a different way from factor VIII). **This is because treatment with bypassing agents may need to change while receiving Hemlibra**. Examples of bypassing agents include activated prothrombin complex concentrate (aPCC) and recombinant FVIIa (rFVIIa). Serious and potentially life-threatening side effects can occur when aPCC is used in patients who are also receiving Hemlibra:

What do I do if I develop a breakthrough bleed while on Hemlibra?

Hemlibra is not to be used to treat a bleeding episode.

Using a bypassing agent while receiving Hemlibra

Before you start using Hemlibra, talk to your doctor and carefully follow their instructions on when to use a bypassing agent and the dose and schedule you should use. Hemlibra increases the ability of your blood to clot. Therefore, the dose of bypassing agent required may be lower than the dose you used before starting Hemlibra.

- Use aPCC only if no other treatment can be used. If aPCC is required, talk to your doctor in case you feel you need a total of more than 50 units/kg of aPCC.
- Despite limited experience with concomitant administration of anti-fibrinolytics 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 rFVII

Potentially serious side effects of using aPCC while receiving Hemlibra

Destruction of red blood cells (thrombotic microangiopathy)

- This is a serious and potentially life-threatening condition.
- When people have this condition, the lining of the blood vessels can be damaged and blood clots may develop in small blood vessels. In some cases, this can cause damage to the kidneys and other organs.
- Be cautious if you are at high risk for this condition (have had this condition in the past, or a member of your family have suffered from it), or if you are taking medicines that can increase the risk of developing this condition, such as ciclosporin, quinine or tacrolimus.
- It is important to know the symptoms of thrombotic microangiopathy, in case you develop the condition (see section 4 of the PIL, “Possible side effects” for a list of symptoms).

Stop using Hemlibra and aPCC, and talk to a doctor immediately if you or your caregiver notices any symptoms of thrombotic microangiopathy.

Blood clots (thromboembolism)

- In rare cases, a blood clot can form inside blood vessels and block them, which may be life-threatening.
- It is important to know the symptoms of such internal blood clots, in case they develop (see section 4, “Possible side effects” for a list of symptoms).

Stop using Hemlibra and aPCC, and talk to a doctor immediately if you or your caregiver notices any symptoms of blood clots in blood vessels..

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 with inhibitors to factor VIII.
- 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 Alert Card?

The Patient Alert 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 Alert Card prior to starting Hemlibra.
- Keep the Patient Alert Card with you all the time - you can keep it in your wallet or purse.
- Show the Patient Alert 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 caregiver or anyone close to you about your treatment and show them the Patient Alert Card because they may notice side effects that you are not aware of.
- Keep the Patient Alert 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?

Call for reporting

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

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. Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal.

You should also report side effects to Roche Products Ltd by emailing the Roche Drug Safety Centre at welwyn.uk_dsc@roche.com or calling +44 (0) 1707 367554. 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 Summary of Product Characteristics (SmPC) or the Patient Information Leaflet (PIL), which are available in all EU/EEA languages on the European Medicines Agency website (www.ema.europa.eu).

Additional information and guidance for patients being prescribed Hemlibra can be found in the Patient Information Leaflet (PIL): www.medicines.org.uk

Company contact point

If you have any questions or problems:

medinfo.uk@roche.com

www.roche.co.uk

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