

MY LIFE WITH **HEMLIBRA®** (emicizumab)

A guide for people with haemophilia A (congenital factor VIII deficiency) with inhibitors to factor VIII who have been prescribed Hemlibra



CHUGAI



My Hemlibra: My guide

You have been prescribed Hemlibra to help manage your haemophilia A with inhibitors.

Inside this booklet, you'll find information to help you get the most from your Hemlibra treatment.

In addition to this booklet, before administering Hemlibra you should read the package leaflet contained in the box with your medicine, the guide for patients/carers and the patient alert card your doctor or nurse will have given to you.

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Getting to know Hemlibra

As you begin a treatment, change can feel both exciting and a little daunting.

It may take a little while for you to get used to your routine with Hemlibra. This booklet is designed to help you understand your condition and how Hemlibra can help you manage it.



Hemlibra is not a cure for haemophilia A. It is a prophylactic treatment used to prevent or reduce the frequency of bleeds



In studies to test Hemlibra, some people had no bleeds requiring treatment while taking Hemlibra¹

**This booklet may not answer all of the questions you have about Hemlibra.
Please ask your doctor or nurse if there's anything else you would like to find out.**

1. Oldenburgh J, et al. *N Engl J Med.* 2017;377:809-18

Haemophilia A

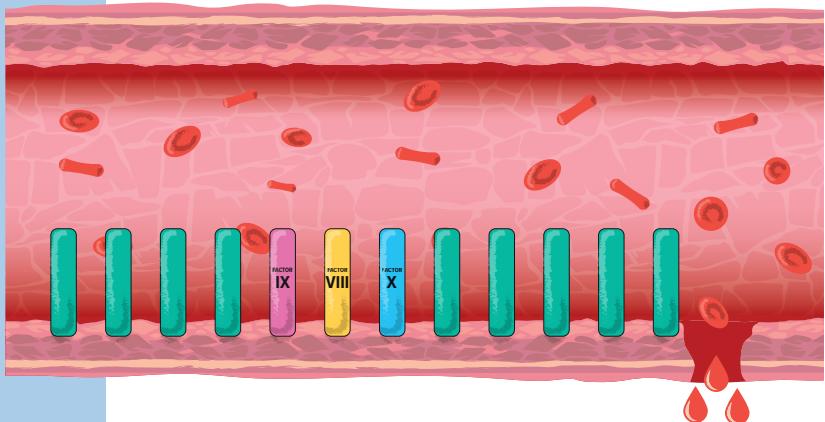
Haemophilia A is a bleeding disorder that means your blood cannot clot properly.

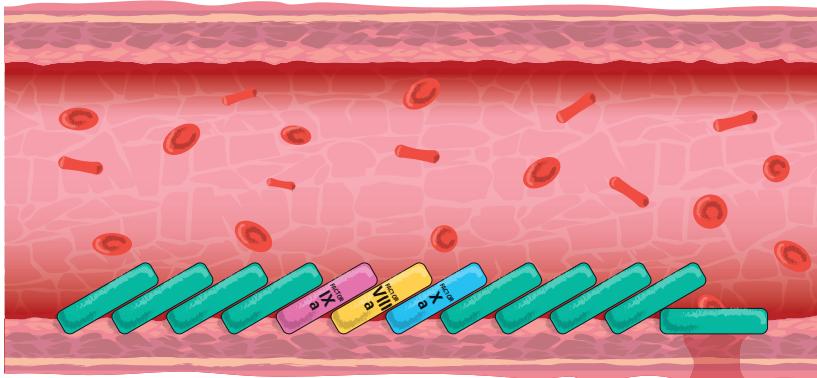
Blood contains lots of clotting factors which interact with each other in a sequence to make a clot form, this is called the 'clotting pathway'.

People with haemophilia A do not have enough of one of these clotting factors – factor eight (factor VIII).

The clotting pathway is a bit like dominoes falling

This illustration represents factors in the clotting pathway that are relevant to haemophilia A.





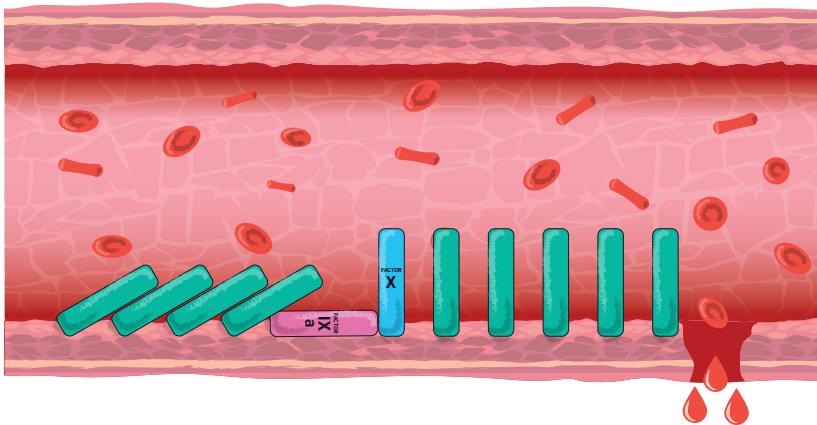
Factor VIII is the link between activated factor nine (factor IXa) and factor ten (factor X).

When factor IXa falls, factor VIII needs to be in place so that it can fall on to the factor X domino.

If factor VIII is missing, the rest of the dominoes will not fall and a clot will not form.

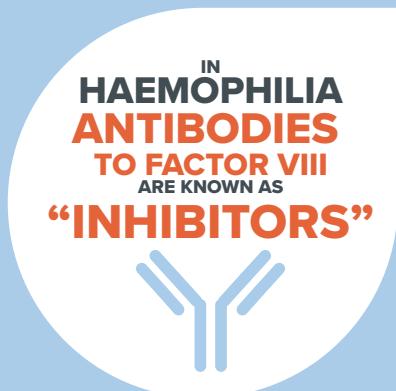
Haemophilia A can be managed with factor VIII replacement therapy.

Factor VIII therapy can be used to help blood clot in response to injury. It can also be administered regularly, to help prevent bleeds from happening. Taking a treatment regularly to try and prevent bleeding is called prophylaxis.



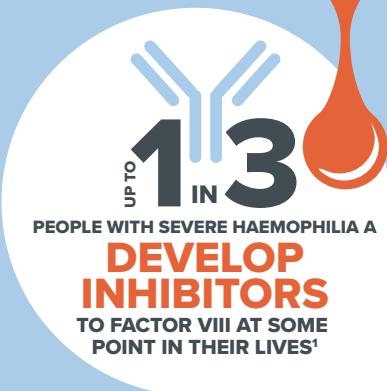
Haemophilia A with inhibitors to factor VIII

Factor VIII replacement therapy is not made in your body. Your immune system can therefore treat it as 'foreign' and develop antibodies against factor VIII.



INHIBITORS REDUCE THE EFFECT OF FACTOR VIII REPLACEMENT THERAPY

In some people, inhibitors can stop factor VIII replacement therapy from working



1. Meeks SL, et al. *Hematology Am Soc Hematol Educ Program*. 2016 Dec 2;2016(1):657-662.

...bypassing agents are used to help manage bleeds. These include activated recombinant factor VII (rFVIIa, Novoseven) activated prothrombin complex concentrate and activated prothrombin complex concentrate (aPCC, Feiba)

Understanding how Hemlibra works

Antibodies are proteins made by the body that stick to substances (antigens). Antibodies can be important in fighting infection. However, they can also be designed to bind to specific substances to manage diseases; these are called monoclonal antibodies.

Hemlibra is a monoclonal antibody designed to help prevent bleeding in people with haemophilia A with inhibitors to factor VIII.

- Hemlibra is a bispecific antibody, meaning it can bind to two different substances
- Hemlibra binds to factor IXa and factor X. This forms a link so the clotting pathway can continue
- Hemlibra is not the same as factor VIII replacement therapy, so it is not thought that factor VIII inhibitors will affect Hemlibra

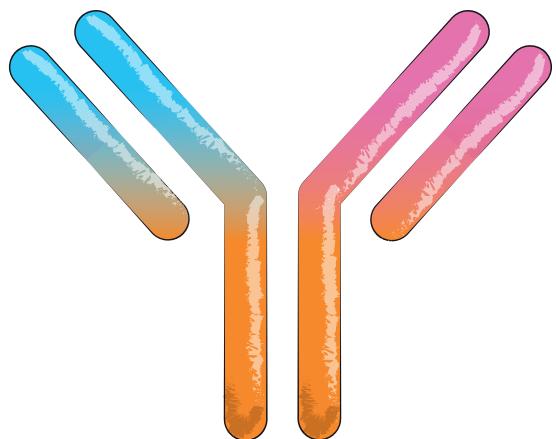
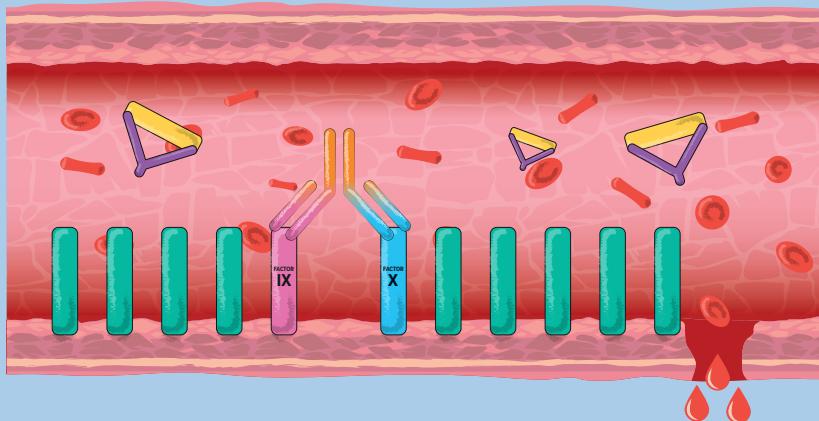


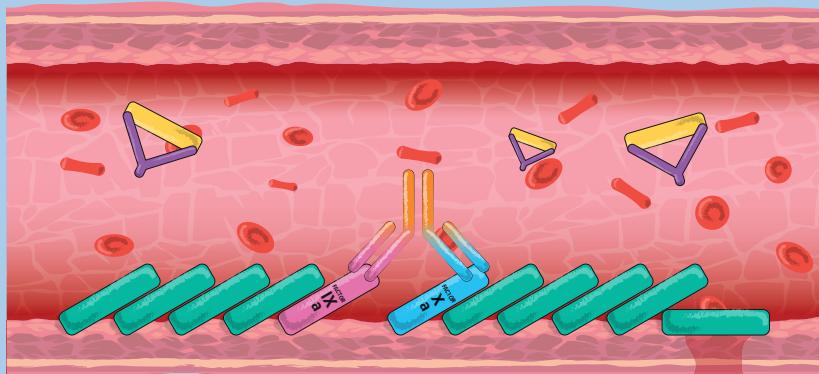
Diagram of the Hemlibra monoclonal antibody



Remember the dominoes?

When your immune system creates antibodies against factor VIII, these inhibitors stick to the factor VIII in your blood and stop the factor VIII from working.

However, Hemlibra binds to activated factor IXa and factor X, bridging the gap so the clotting pathway can continue and a clot can form.



How to take Hemlibra

Hemlibra must be taken regularly as prophylaxis. Your dose is based on your body weight.

Any treatment with bypassing agents (e.g. aPCC, Feiba and rFVIIa, NovoSeven) should be discontinued the day before starting Hemlibra.

LOADING DOSE

For the first 4 weeks, you take a loading dose of Hemlibra.



ONGOING DOSE

From week 5, you carry on with a regular ongoing dose.



OR



OR

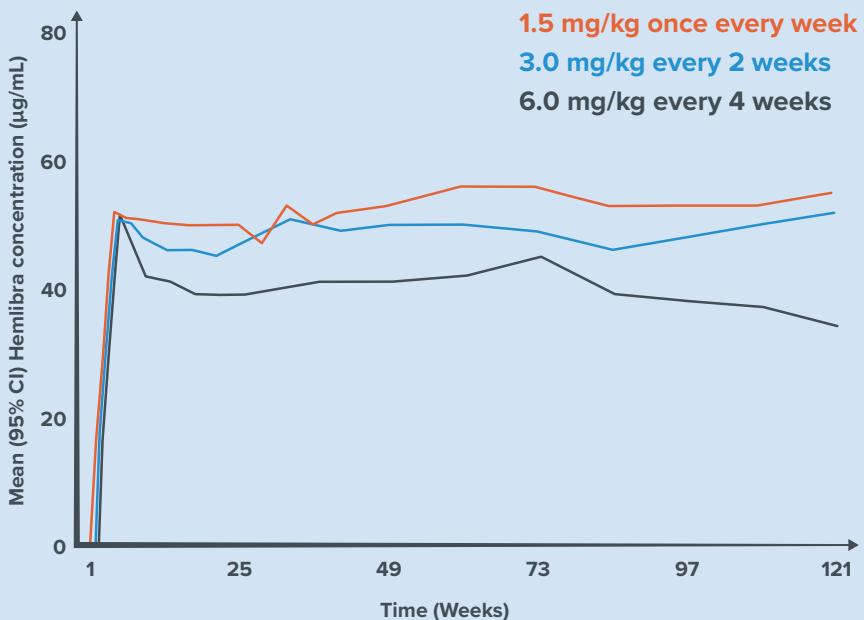


How to take Hemlibra

Taking Hemlibra regularly maintains a consistent level in your blood

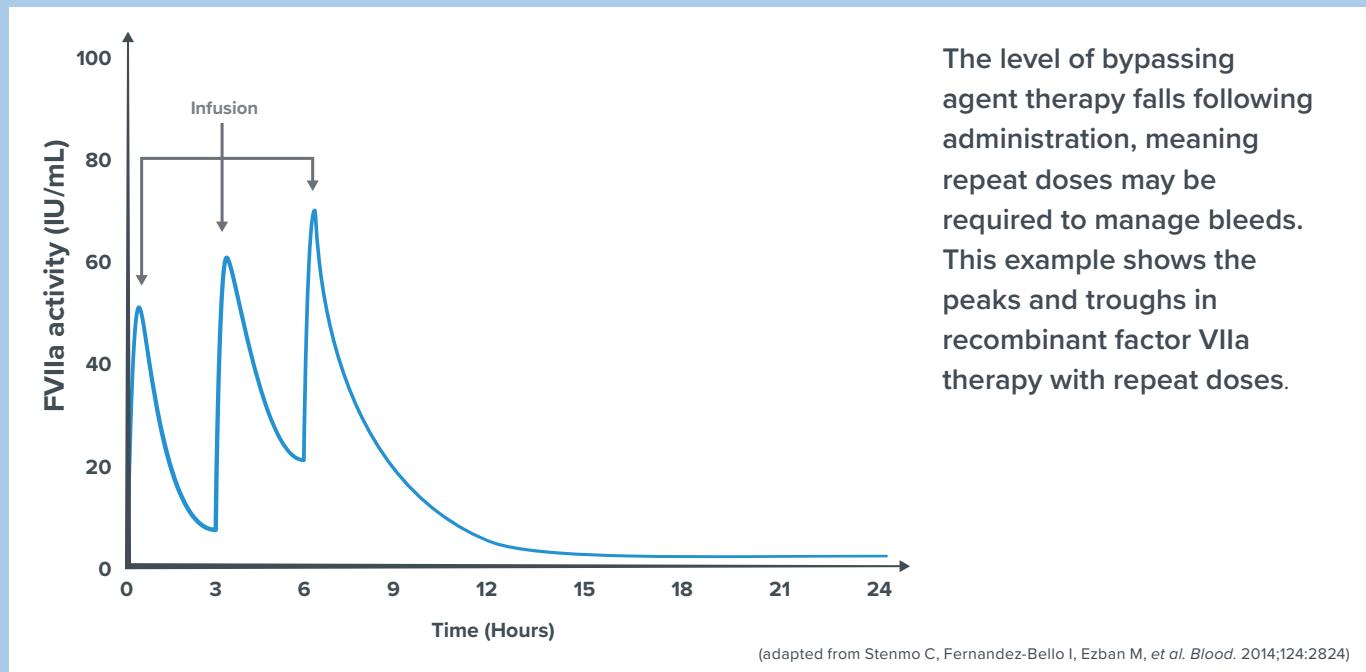
After the initial loading dose, blood levels of Hemlibra remain stable between doses, whether you are taking your ongoing dose once every week, every 2 weeks, or every 4 weeks.

This means that you do not need to take additional doses of Hemlibra to cover any planned physical activity.



(adapted from Callaghan *et al*, *blood* 2021)

Bypassing agents



How to take Hemlibra

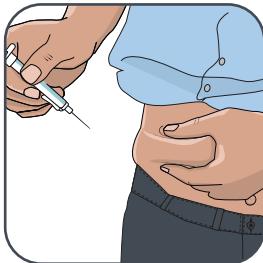
Hemlibra is given as an injection under the skin, called a **subcutaneous injection**. This may be different from what you're used to.

- Your haemophilia team will teach you how to perform subcutaneous injections
- Your haemophilia team will calculate your dose of Hemlibra based on your weight
 - Let them know if you lose or gain weight so that they can adjust your Hemlibra dose
 - Do not try to calculate your dose of Hemlibra yourself
- The acronym PARIS can help you to remember each step correctly and make injecting Hemlibra more comfortable

AS A REMINDER, there are detailed instructions in the Hemlibra package leaflet that comes with your medication. This includes how to prepare your vial(s) and how to inject Hemlibra. **A reminder video is available online at www.takingemicizumab.com. You can also access this from the QR code printed on the last page of this booklet.**

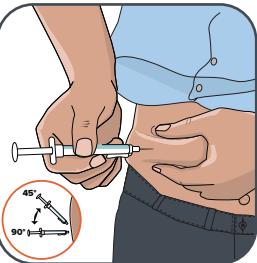
P A R I S

PINCH



Pinch the skin at the selected injection site.

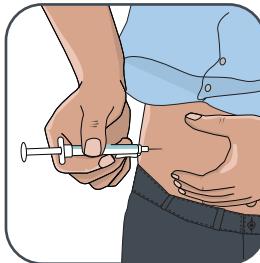
ANGLE



Angle the needle at 45° to 90° and insert with a quick, firm action.

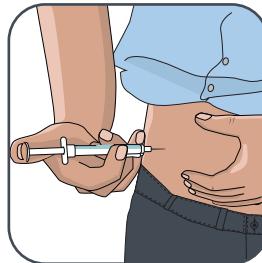
Do not hold or push on the plunger while inserting the needle.

RELEASE



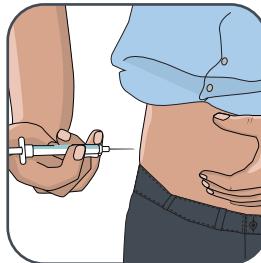
Release the pressure between the pinched skin whilst holding the syringe still, in the same position.

INJECT



Inject all the prescribed dose slowly by gently pushing the plunger all the way down.

SLIDE



Slide the needle gently out from the injection site at the same angle as inserted.

Preparing for Hemlibra injections

- Wash your hands well with soap and water before preparing and administering Hemlibra
- Before use, allow the vial(s) to reach room temperature for about 15 minutes on a clean flat surface away from direct sunlight
- For each injection, use a different area of the body to the one you used last time. You should use a different injection site for each injection, at least 2.5cm away from the area you used for your previous injection. This also applies if you need to have more than one injection for your prescribed dose
- Clean the chosen injection site area using an alcohol wipe and let the skin dry for at least 10 seconds

Tips for remembering your injections



Set reminders on your phone or computer.



Schedule your injection day around a regular activity.

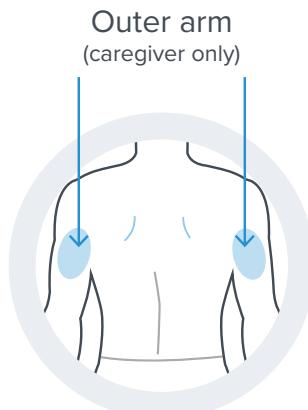
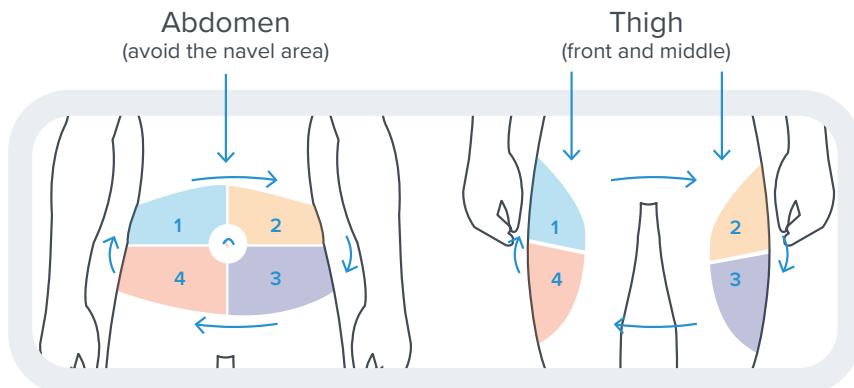
Continue to use Haemtrack® to keep a record of each time you use Hemlibra.

Where to inject Hemlibra

The recommended injection sites are the abdomen and thigh. Additionally, the outer arm, when administered by a caregiver.

These sites are recommended because they have an easily accessible area of fatty tissue just below the skin.

Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or if the skin is broken



Getting started

Hemlibra is always prescribed as routine prophylaxis. It is essential to take Hemlibra regularly to have a better chance of preventing bleeds.

DOs



Take Hemlibra regularly as instructed



Continue to take Hemlibra, even if you haven't had a bleed in a while



If your prescribed dose is more than 2 mL you will need to have more than one subcutaneous injection of Hemlibra. These injections must be given on the same day with each injection at least 2.5 cm away from the area used for the previous one

DON'Ts



Do not take extra Hemlibra, even if you do have a bleed



Do not adjust your dose of Hemlibra yourself

Continuing Hemlibra

Once you have taken Hemlibra for 4 weeks at the loading dose you will continue to inject Hemlibra regularly, as instructed by your haemophilia team.

Regular blood tests to check your factor levels are not needed when you are taking Hemlibra. Your dose is not based on your clotting factor levels.

If you do need to have any laboratory or blood tests, tell your doctor you are taking Hemlibra, as it can interfere with some laboratory tests, leading to inaccurate results.



Hemlibra clinical trials



Hemlibra has been tested in clinical trials with people with haemophilia A with inhibitors to factor VIII.

Hemlibra treatment was tested in people who previously used either:



On-demand treatment with bypassing agents

OR



Prophylaxis with bypassing agents

Findings from these clinical trials suggest that taking Hemlibra can help prevent bleeding or reduce the number of bleeding episodes

Oldenburg J, et al. *N Engl J Med.* 2017;377:809–818

Possible side effects

Like all medicines, Hemlibra can cause side effects, although not everyone gets them.

● Very common: may affect more than 1 in 10 people

- A reaction in the area where the injection is given (redness, itching, pain)
- Headache
- Joint pain

● Common: may affect up to 1 in 10 people

- Fever
- Muscle aches
- Diarrhoea
- Itchy rash or hives (urticaria)
- Skin rash

● Uncommon: may affect up to 1 in 100 people

- Destruction of red blood cells (thrombotic microangiopathy)
- Blood clot in a vein behind your eye (cavernous sinus thrombosis)
- Severe damage of the skin tissue (skin necrosis)
- Blood clot in a vein near the surface of the skin (superficial thrombophlebitis)
- Swollen face, tongue and/or throat and/or difficulty in swallowing, or hives, together with difficulty in breathing which are suggestive of an angioedema
- Lack of effect or decreased response to treatment
- Allergic reaction

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. Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, or the free Yellow Card app available in the Apple App Store or Google Play Store. 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.

Other important information about Hemlibra

Antibody formation (immunogenicity)

You may notice that bleeding is not being controlled with your prescribed dose of Hemlibra. This could be due to the development of antibodies to this medicine.

Talk to your doctor immediately if you notice an increase in bleeds. Your doctor may decide to change your treatment if this medicine stops working for you.

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. Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, or the free Yellow Card app available in the Apple App Store or Google Play Store. 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.

Using bypassing agents with Hemlibra

In clinical trials, serious side effects were seen in patients using aPCC (Feiba) while receiving Hemlibra. Use of aPCC should be avoided unless no other treatment options/alternatives are available.

If aPCC is needed while you are using Hemlibra, an initial dose of no more than 50 units/kg should be used. If bleeding is not controlled, additional aPCC should only be administered under medical guidance/supervision. The total dose of aPCC should not exceed 100 units/kg in the first 24-hours of treatment.

Stop using Hemlibra and aPCC and talk to a doctor immediately if you or your caregiver notices any of the following side effects:

- **Destruction of red blood cells (thrombotic microangiopathy, TMA):**
 - 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 TMA
- **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

IF YOU NEED TO GO TO HOSPITAL FOR A BLEED,

make sure you tell the healthcare team that you are taking Hemlibra. Remember to take your patient alert card with you. Refer to your emergency plan on page 22.

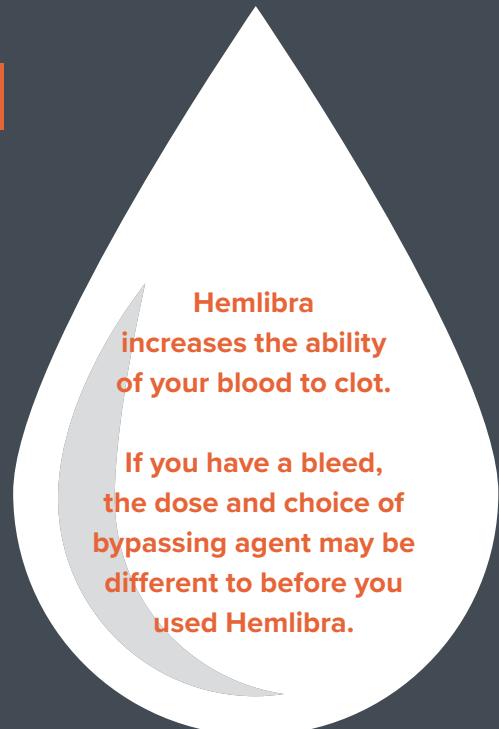
For more information on TMA or thromboembolism, please speak to your healthcare provider.

Being prepared to manage a bleed

IF YOU HAVE A BLEED, DO NOT TAKE EXTRA HEMLIBRA

- It is very important you know how to manage a bleed while you are taking Hemlibra
- If your bleed requires treatment, you will need to use a bypassing agent. Your haemophilia team will explain when to treat a bleed and the correct dose of bypassing agent to use.
- If you are using HealthID or have a MedicAlert Bracelet or necklace, you could consider updating your information

The package leaflet contained in the box with your medicine, the guide for patients/carers and patient alert card also have guidance for using bypassing agents while you are taking Hemlibra



What to do if you have a bleed while taking Hemlibra

Please keep this booklet in a safe place so you can refer back to your emergency plan. There is space to write down your contacts and for your doctor or nurse to write down a reminder of your personalised plan for what to do if you have a bleed.

Emergency contacts:

In an emergency:

Remember to keep this updated, if anything changes.

Signed:

Also refer to information on page 20 of this booklet about using bypassing agents while you are taking Hemlibra.

Frequently asked questions

Storing your Hemlibra

How do I store Hemlibra at home?

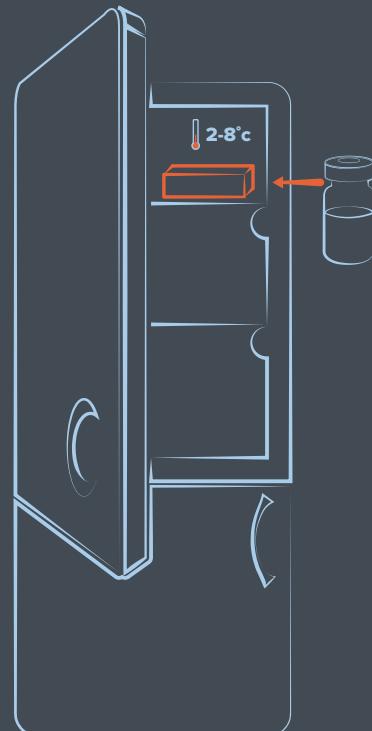
Store Hemlibra in your fridge between 2°C and 8°C in the original box to protect from light. Do not freeze Hemlibra and do not shake the vials. Keep out of the sight and reach of children. Do not use after the expiry date stated on the side of the box and the vial label (the date refers to the last day of the month). Speak to your haemophilia centre if you would like more information on storing medications at home.

Can I take Hemlibra out of the fridge?

Once removed from the fridge, unopened vials can be kept at room temperature (below 30°C) for a total of 7 days. Discard any vial that has been kept at room temperature for more than 7 days or has been in temperatures above 30°C.

Where should I keep my injection supplies?

Keep injection equipment safe and stored away in a cool, dry environment. It is a good idea to keep everything together in a box. Make sure that all supplies are kept out of the sight and reach of children.

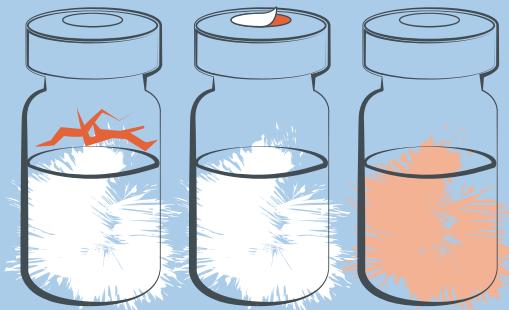


Frequently asked questions

Injecting Hemlibra

Who should I tell if I'm having trouble with subcutaneous injections?

Once you have been trained you should be able to inject Hemlibra at home by yourself or with the help of a caregiver. Tell your doctor or nurse if you are not confident with performing subcutaneous injections.



What if I break a vial or it's not sealed well?

Inspect each vial before use. Do not use if they appear damaged, the cap covering the stopper is missing or if they have been dropped. Contact your haemophilia centre and provide the batch details of the affected vial. Keep the vial in the correct storage conditions as you may need to return it.

What if the liquid looks strange?

Before using Hemlibra, check the solution for particles or discolouration. The solution should be colourless to slightly yellow. Do not use if it is cloudy, hazy, discoloured or contains visible particles. Contact your haemophilia centre and provide the batch details of the affected vial. Keep the vial in the correct storage conditions as you may need to return it to your centre.

I'm having trouble drawing up the liquid (getting it into the syringe).

Hemlibra is a viscous liquid, which means it is quite thick. Initially, you might find it difficult to draw it up into the syringe until you get used to it. Talk to your doctor or nurse if you continue to struggle.

Do I have to wait to have the injection after drawing up the solution in to the syringe?

No. Once the syringe has been filled with Hemlibra, the injection must be given immediately. Do not refrigerate the solution in the syringe.

How should I dispose of my sharps, needles, and used vials?

Put any used vials, needles, vial/injection needle caps and used syringes in a sharps bin.

Can I save a part-used Hemlibra vial for my next injection?

No. Only use the vial once. After you inject your dose, throw away any unused Hemlibra left in the vial.

I keep getting soreness after injections, what should I do?

Injection site reactions are a very common side effect that some people get with Hemlibra. Make sure that you rotate the injection site with each injection. If you have signs of redness, itching or pain at the injection site, tell your doctor or nurse.



Frequently asked questions

Taking Hemlibra

Should I tell people I have started taking Hemlibra/changed medications?

Your regular haemophilia A care team and your GP will be updated when you change medications. If you have a MedicAlert bracelet or necklace, or a Health ID profile, you could consider updating your information. It is up to you whether you want to tell your friends and family about your treatment, but it may help to talk to people that are close to you so that they can support you. It's a good idea to carry information about your medicines, such as your alert card, in case you see a different doctor, or need to see a doctor when you are away from home.

Can I get blood-borne diseases from Hemlibra?

Hemlibra is a therapeutic antibody made in the laboratory. It is not made from other people's blood or plasma, so there is very little risk of developing a blood-borne disease.

Are there any other medications that I should not take with Hemlibra, or need to be careful with?

There have not been any studies to specifically test how Hemlibra interacts with other medications. Stop taking any treatment with bypassing agents (aPCC, Feiba and rFVIIa, NovoSeven) the day before starting Hemlibra.

Because Hemlibra helps your blood to clot, taking other clotting medicines at the same time can make the blood clot too much. Clinical experience indicates Hemlibra interacts with aPCC. Serious and potentially life-threatening side effects can occur when aPCC is used in people who are also receiving Hemlibra. Use of aPCC should be avoided unless no other treatment can be used. You should only use aPCC if advised to do so by your haemophilia care team. See page 20 of this booklet, the package leaflet contained in the box with your medicine, the guide for patients/carers and patient alert card for additional information.

Can I take more Hemlibra if I wake up with pain?

No. If you think that you are having a bleed, you must not take extra Hemlibra. You may need to talk to your doctor or nurse if the pain is severe.

Should I take more Hemlibra if I am going to play sport?

No, Hemlibra is not an on-demand treatment. Prophylaxis with Hemlibra maintains a consistent level in your blood between doses for the whole time that you are on treatment.

After I have started Hemlibra, should I take factor VIII if I am going to play sport or planning other physical activity?

No. When taken regularly, Hemlibra levels are stable, without any peaks and troughs. This means you should not 'top up' your treatment to cover any physical activity unless you have been specifically told to by your doctor or nurse.

Can I stop taking Hemlibra if I haven't had a bleed for a while?

Great news that you haven't had a bleed in a while! However, you still need to keep taking Hemlibra so that you are protected from future bleeding episodes. Do not stop taking Hemlibra without talking to your doctor or nurse.

I want to start a family, is this OK while taking Hemlibra?

Ask your doctor or nurse for advice before using this medicine if you are trying to conceive. There are no clinical studies of Hemlibra use in people trying to conceive, or of Hemlibra in people who are pregnant.

Can I combine Hemlibra doses?

Different Hemlibra concentrations (30 mg/mL and 150 mg/mL) should not be combined in a single injection when making up the total volume to be injected.

What should I do if I forget to take Hemlibra?

If you forget your scheduled injection, inject the forgotten dose as soon as possible up to the day before the day of the next scheduled dose. Then, inject Hemlibra as scheduled. Do not inject two doses on the same day to make up for a forgotten dose. If you are not sure what to do, ask your doctor or nurse.

How long will I be on Hemlibra for?

Hemlibra is intended for long-term treatment. Usually you will continue taking Hemlibra as long as you and your haemophilia team are happy with how your treatment is going. Some people have been on Hemlibra for over seven years.

Can I drive or use machines while taking Hemlibra?

Hemlibra is not likely to affect the ability to drive or use machines.

Frequently asked questions

Travelling with Hemlibra

What do I need to know when travelling with Hemlibra?

If you need to travel with Hemlibra, remember that it can remain out of the fridge for up to 7 days if necessary. However, it is recommended that you store your Hemlibra vials in a fridge whenever possible, even when travelling. Remember to also take your injection supplies and sharps bin with you to safely dispose of your used syringes, needles and vials.

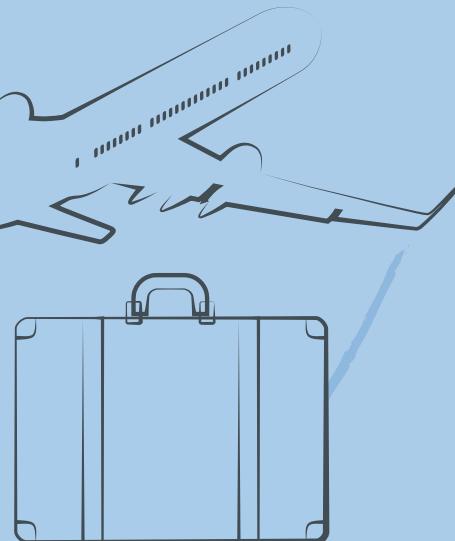
Can I take Hemlibra on an aeroplane?

If you are travelling by aeroplane your doctor or nurse may provide a letter to

give to the airline. If you are on a long flight, the airline may be able to store your medication in a fridge. You should carry your Hemlibra vials with you in your hand luggage so they are not damaged during the flight.

What about my bypassing agent?

You may need to carry supplies of bypassing agent in case you have a bleed. You will need to carry this in your hand luggage as well. Check the product information provided with the bypassing agent and/or talk to your nurse or doctor.



REMEMBER, you should also carry your bypassing agent, and supplies to manage a bleed, in case you have one.

Lifestyle

Should I change my diet?

You do not need to change your diet when you are taking Hemlibra, but it is important for anyone with haemophilia A to try to be as healthy as possible; eat well and keep hydrated. The Haemophilia Society and the World Federation of Hemophilia have lots of resources on trying to maintain a healthy diet.

Can I drink alcohol?

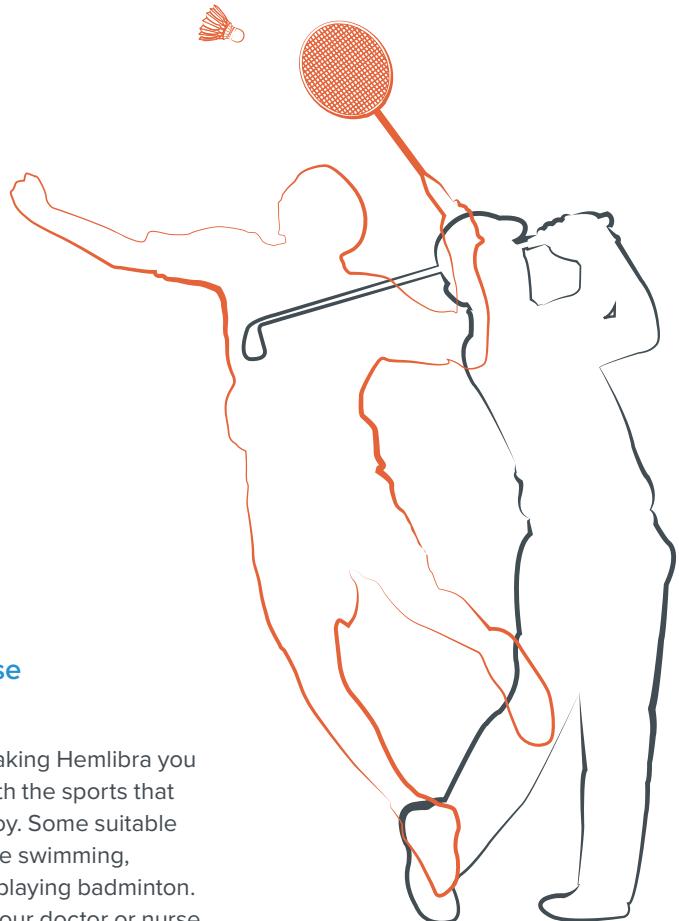
Hemlibra is not affected by drinking alcohol, however it is recommended you stick to government alcohol limits and unit guidelines.

Is smoking OK?

The effects of smoking when taking Hemlibra have not been tested. However, it is best to stay healthy when you have haemophilia A. If you are a smoker, you could consider speaking to your doctor or nurse about ways to reduce or stop smoking.

What exercise is OK to do?

While you are taking Hemlibra you can carry on with the sports that you usually enjoy. Some suitable activities include swimming, cycling, golf or playing badminton. Always talk to your doctor or nurse before starting new activities¹.



1.Srivastava A, et al. *Haemophilia*. 2013;19:e1–47

Glossary

Hemlibra is a medicine for haemophilia A with inhibitors to factor VIII that works in a different way to other treatments that you might have been prescribed in the past. Understanding how it works and how it can help you may take a little time.

Here are the meanings of some medical terms for you to learn, or to refresh your memory:

Antibody

Proteins produced by the immune system that bind to unwanted substances to help the body to remove them.

aPCC

Activated prothrombin complex concentrate (aPCC) is a bypassing agent for people with haemophilia A with inhibitors to factor VIII. It contains a mixture of different clotting factors.

Bypassing agent

A type of treatment given to people with inhibitors to factor VIII. Bypassing agents help the blood form a normal clot by going around (or bypassing) the factor VIII that has been inhibited.

Clotting

The process by which blood changes from a liquid to a solid, forming a blood clot.

Clotting pathway

The sequence in which clotting factors interact with each other in order to form a clot.

Factor

There are a number of essential blood-clotting proteins in the blood known as factors.

Factor VIII

The essential blood-clotting protein that is reduced or missing in people with haemophilia A.

Factor VIII replacement therapy

A treatment that replaces the low or missing factor VIII in people with haemophilia A. Factor FVIII replacement therapy can be used to help manage a bleed, and it can also be taken regularly as prophylaxis to help prevent bleeds.

Haemophilia A

A bleeding disorder where factor VIII is either partly or completely missing. Haemophilia A can be classed as mild, moderate or severe depending on the amount of factor VIII available in the blood.

Immune system

The cells and tissues in the body that provide protection from infections and foreign substances.

Inhibitor

A type of antibody that prevents factor VIII replacement therapy from working.

On-demand

The use of a treatment as needed. In haemophilia A with inhibitors to factor VIII, bypassing agents are given immediately after a bleed is recognised to help clotting and stop bleeding.

Prophylaxis

The regular use of a treatment to prevent illness. In haemophilia A, prophylaxis is intended to prevent bleeding from occurring or reduce the number of bleeds.

Subcutaneous Injection

A method to deliver medicine into the body that involves inserting a needle into the tissue just beneath the skin.

Therapeutic antibody

Therapeutic antibodies, often referred to as monoclonal antibodies, are designed to bind to specific molecules to help treat a disease or condition.



For a reminder video on how to administer Hemlibra, access www.takingemicizumab.com using the QR code here

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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. Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, or the free Yellow Card app available in the Apple App Store or Google Play Store. 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.