

Haemoquest

ADVENTURES IN HAEMOPHILIA A

A guide for people with severe haemophilia A (congenital factor VIII deficiency, FVIII <1%) who do not have inhibitors to factor VIII and who have been prescribed Hemlibra® (emicizumab)



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HI!

I'M JACK AND
I HAVE SEVERE
HAEMOPHILIA A.
I AM ABOUT TO
START A MEDICINE
CALLED HEMLIBRA

Your guide to Hemlibra

You have been prescribed Hemlibra because you, your doctor and the people who look after you have decided it is the right treatment to help manage your severe **haemophilia A**.

Although Hemlibra is also used for people who have **inhibitors** to factor VIII, this **does not** mean you have inhibitors to factor VIII. If you are worried about this, talk to your doctor or nurse.

Inside this booklet, we'll go on a quest to collect the information you may need to know about taking Hemlibra.

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HaemoQuest

Starting a different treatment for severe haemophilia A can be exciting but it might be confusing to begin with. HaemoQuest will help you learn a bit about Hemlibra so that you can get the most out of your treatment.



Hemlibra is not a cure for your severe haemophilia A but, when it is taken regularly, which is also referred to as **prophylaxis (pronounced pro-fi-lax-is), Hemlibra might reduce the number of bleeds you have¹**

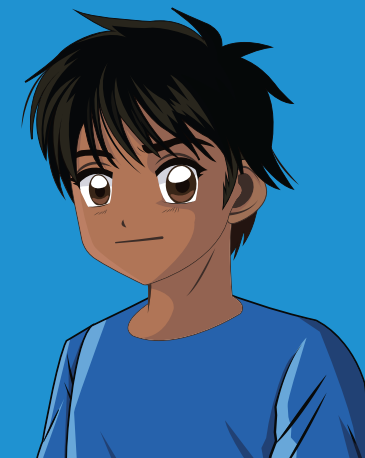


This booklet contains lots of information about Hemlibra, but may not answer all your questions

- 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 patient alert card your doctor or nurse will have given to you, or the person who looks after you
- You can also talk to your doctor or nurse if there is anything else you would like to find out

Who else can help you to learn about Hemlibra?

Reference: 1. Mahlangu J, et al. *N Engl J Med*. 2018;379:811-822



DUDE!

I'M SAM, JACK'S
BEST FRIEND. WE'RE
GOING ON A QUEST
TO LEARN ABOUT
JACK'S MEDICINE.
COME AND HELP US!

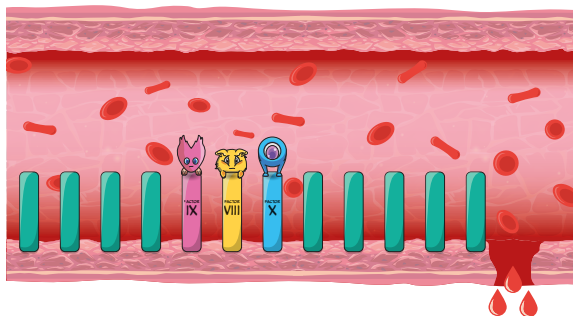


LET'S GO!

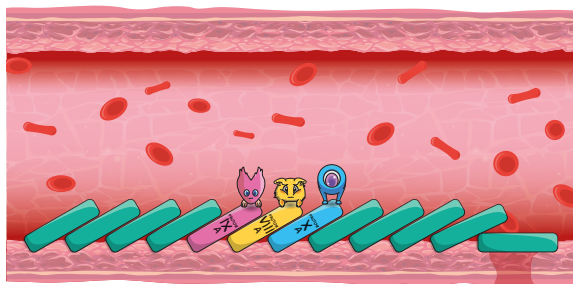
LET'S FIND OUT
MORE ABOUT
HAEMOPHILIA A

What is haemophilia A?

There are things in your blood called **clotting factors** that work together to make a clot. Three of these are **factor IXa** (pronounced activated factor 9), **factor VIII** (pronounced factor 8) and **factor X** (pronounced factor 10)

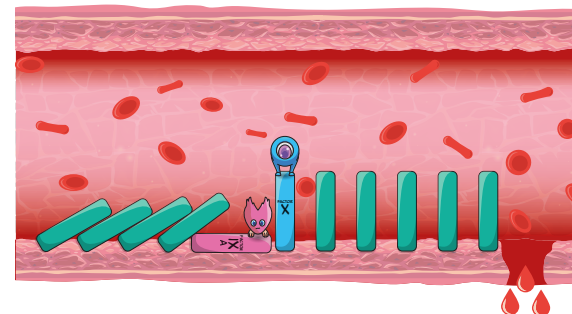


Clotting factors interact with each other in a sequence – think of them like a set of dominoes.



Each clotting factor switches on the next one. When all the clotting factors have been switched on a clot is formed.

If you have haemophilia A, your blood does not clot properly. People with haemophilia A do not have enough of one of these blood clotting factors called **factor VIII**.



This is a bit like having a domino missing.

Haemophilia A is described as mild, moderate or severe, depending on how much factor VIII is in the blood. People with severe haemophilia A, like you and Jack, have less than 1% factor VIII.

Factor VIII replacement therapy is used to replace missing factor VIII. It can help make your blood clot and stop bleeds. You may have already tried using factor VIII replacement therapy to treat a bleed, or may have taken it regularly to try and prevent bleeds from happening.



HELLO!

I'M DR PHILLIPA,
THE CLOTTING
PATHWAY IS A BIT LIKE
DOMINOES FALLING.

CAN YOU MAKE A
DOMINO CASCADE?



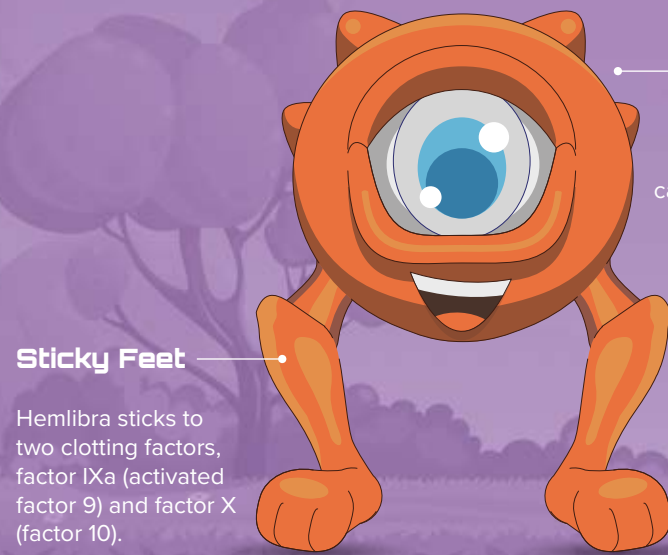
SO...

HEMLIBRA CAN
HELP THE BLOOD
TO CLOT EVEN IF
YOU HAVE SEVERE
HAEMOPHILIA A!

Antibodies

Antibodies are a normal part of your blood that help fight infection. They help to protect you by recognising and sticking to things that shouldn't be in your body, such as bacteria or 'germs'.

Antibodies can also be made in a laboratory and used as medicines.



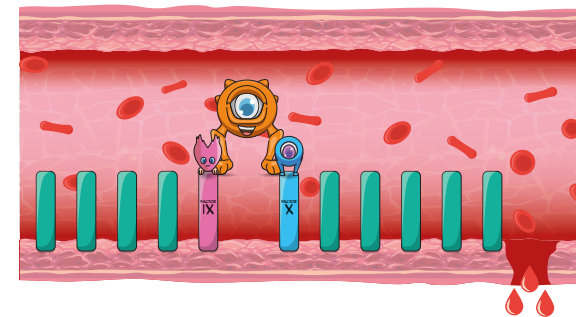
Sticky Feet

Hemlibra sticks to two clotting factors, factor IXa (activated factor 9) and factor X (factor 10).

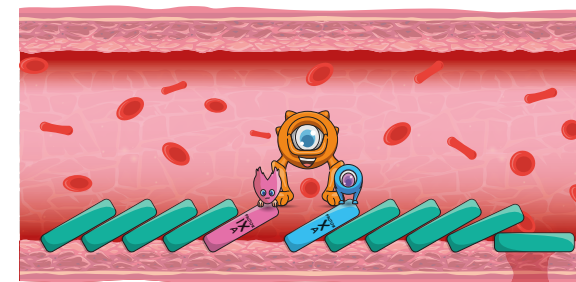
Hemlibra

Dr Phillipa has designed an antibody called Hemlibra that can help people with severe haemophilia A.

How does Hemlibra work?

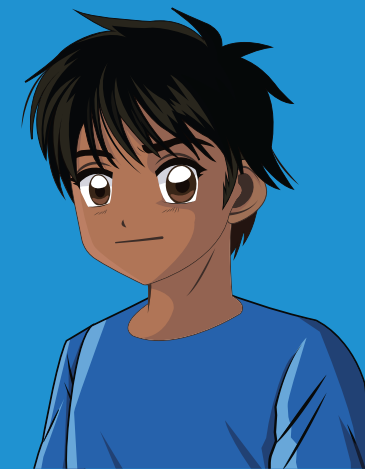


Hemlibra is different, as it doesn't try to replace your missing factor VIII. Instead, Hemlibra creates a bridge between factor IXa and factor X, that you do have in your blood.



By creating this bridge Hemlibra allows the rest of the clotting factors to continue working together to form a clot.

Hemlibra is only taken to prevent bleeding. If you have a bleed you might still need factor VIII replacement therapy. There is more information on what to do if you have a bleed on pages 24 – 25 of this book.



GREAT!

HEMLIBRA BRIDGES
THE GAP BETWEEN
THE DOMINOES TO
COMPLETE THE FALLING
CASCADE

HEMLIBRA IS
DIFFERENT TO FACTOR VIII
REPLACEMENT THERAPY
IT IS DESIGNED TO GIVE
YOU STABLE LEVELS
BETWEEN DOSES

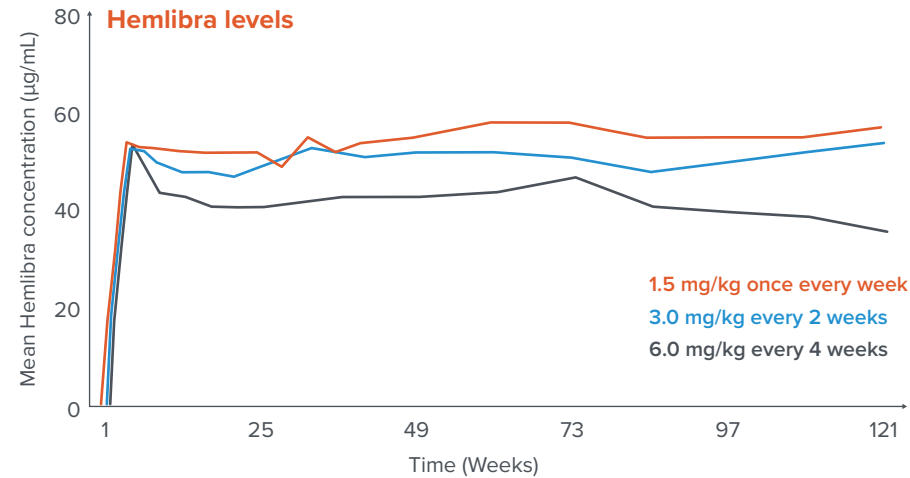


The science part

Hemlibra

After the initial four starting (also called loading) doses of 3.0 mg/kg once a week, you will take Hemlibra once every week, once every 2 weeks, or once every 4 weeks, depending on the schedule you and your doctor or nurse have decided on.

Hemlibra levels remain stable between doses. **This means that you do not need to take additional doses of Hemlibra or factor VIII replacement therapy to cover activities such as playing sport.**



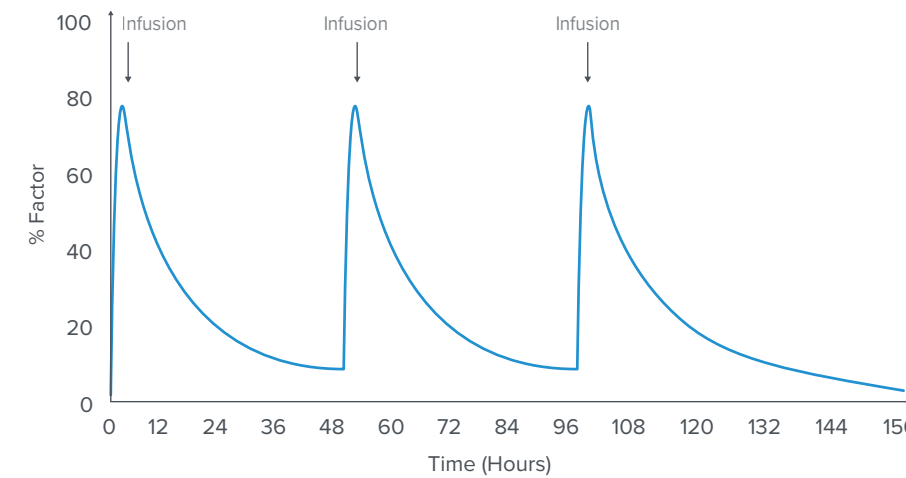
(adapted from Callaghan et al, blood 2021)

Factor VIII replacement therapy

With factor VIII replacement therapy, the level of factor VIII rises quickly after infusion and then decreases, as shown by the peaks and troughs on the graph. This means that if you were taking factor VIII replacement therapy regularly, you may have needed to take additional doses, for example if you were playing sport.

Factor VIII levels after IV administration

(note; this does not refer to a specific factor VIII product)



(adapted from Castaman G, Linari S. *Expert Opin Drug Metab Toxicol.* 2018; 14: 143-151)



COOL!

REMEMBER, YOU DON'T
TAKE ADDITIONAL
HEMLIBRA WHEN
YOU WANT TO GO
AND PLAY SPORTS



GET INTO A ROUTINE!

DON'T FORGET TO TAKE
HEMLIBRA REGULARLY
AS INSTRUCTED
BY YOUR DOCTOR
OR NURSE

Taking Hemlibra

Hemlibra must be taken regularly to help prevent bleeds.
This type of treatment is called **prophylaxis**.



Your doctor or nurse will tell you how often to take your Hemlibra.
It is important that you try not to forget any injections so that you
have a better chance of preventing bleeds

You, or the person who looks after you should record your treatment
in the Haemtrack® app.



Take Hemlibra regularly, as instructed, even if you have not
had a bleed in a while



Do not take extra Hemlibra if you have a bleed



Do not change the dose or frequency of Hemlibra unless your doctor
or nurse tells you to

ARCHERY KGB JTNL JBFEGBIMLP
IMNGVBKNBVFNGBADMINTONUM
PJBFBMLMHFVNMLMHGFVHPLN
AUREMIVIDEOGAMESNKMHFEGN
IKLHKUIKHFRHLRJLGOLF TCO
NJUIOGTRFVJOENQUAHPLBGPT
TDTHDIYUOTFGRDOIPNTCRESU
ILJYRCSFHKOPSWIMMINGORS
NAHKOTVEOGIMALPHEVUHEBJR
GIUTRPUTSMTABLETENNISTCA
RFINOQSGHTBINTSIMONTLEDW
OPVEWLEDORVEDOTHQAOTVINI
VESTIUTBEDWALKINGLINTDEN
XIGENLECIEBTSINTECINENFG
OTVPGQUBITNEDSINTHINEDWD
QIBTLIREADINGKOEDINTNEVJ
TKEDVIPRCEGQLICYCLINGLAI

Answers: archery, badminton, golf, swimming, walking, rowing, cycling, table tennis, drawing, painting, reading, video games



WORD UP!

JACK DOES
12 DIFFERENT
ACTIVITIES EVERY
MONTH! CAN YOU
FIND THEM ALL?



Get into a routine with Hemlibra

Using your weight, your doctor or nurse will work out how much Hemlibra you should take.

- **For the first 4 weeks, you take a starting (or loading) dose once a week (3.0 mg/kg)**
- **After that, you carry on taking your normal maintenance dose.** This will be either: (tick your dose schedule as provided by your doctor or nurse)

☐ once every week
(1.5 mg/kg)

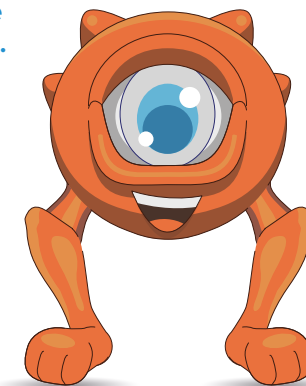
☐ once every 2 weeks
(3.0 mg/kg)

☐ once every 4 weeks
(6.0 mg/kg)

Your doctor or nurse will decide how often you should be weighed. This is a time when you are growing fast, so they need to make sure you are taking enough Hemlibra. Even if your weight does increase, do not change your dose of Hemlibra without talking to your doctor or nurse.

If you have been routinely using factor VIII replacement therapy to prevent bleeds you can continue this alongside Hemlibra for up to 7 days. Your doctor or nurse will tell you when to stop your factor VIII prophylaxis.

If you need to have any laboratory or blood tests, tell the healthcare team that you are taking Hemlibra. Taking this medication can interfere with some of these tests, giving wrong results.



GREAT!

I ALWAYS TAKE MY
HEMLIBRA ON THE SAME
DAY OF THE WEEK AND AT
THE SAME TIME OF DAY
SO IT'S EASY
TO REMEMBER!



REALLY?

WHEN IT WAS BEING
TESTED SOME
PEOPLE WHO TOOK
HEMLIBRA DIDN'T
HAVE ANY BLEEDS

What people say about Hemlibra

Hemlibra has already been tested in people with severe haemophilia A.

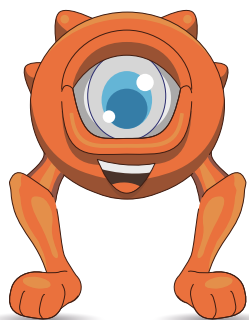
When Hemlibra was taken regularly, people reported:

- ↓ Having less bleeds that needed treatment with factor VIII replacement therapy. Many people did not have any bleeds that needed treatment¹

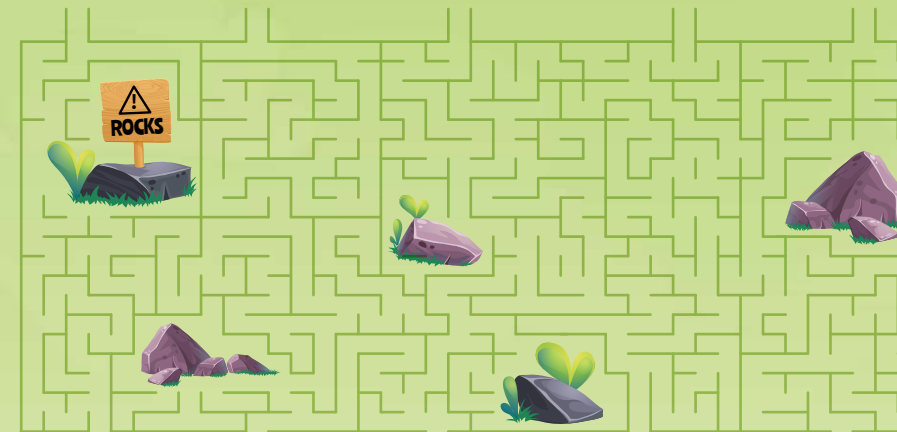
Remember!

- ! Not everyone is the same. Make sure you know what to do if you think you are having a bleed while taking Hemlibra

There is more information on pages 24 – 25 of this book



Reference: 1. Mahlangu J, et al. *N Engl J Med*. 2018;379:811-822



SORTED!

I NEED YOUR HELP TO
MATCH HEMLIBRA AND
THE CLOTTING FACTORS
TO THEIR OUTLINES...

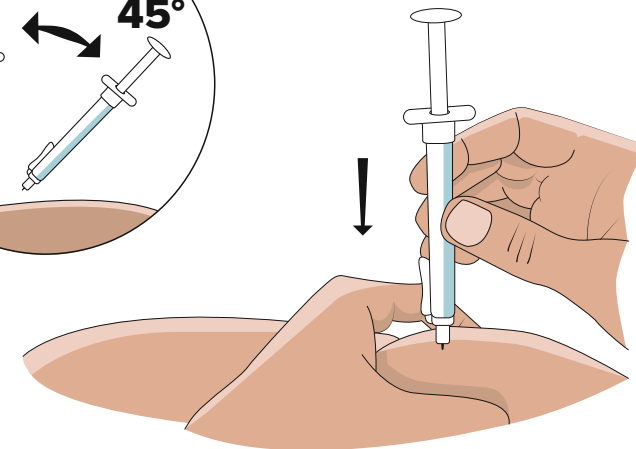
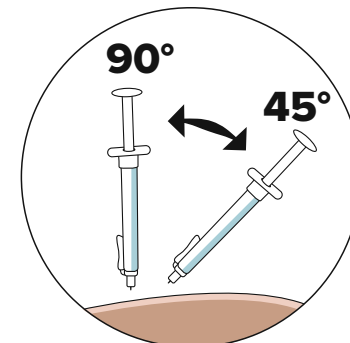
REMEMBER TO AVOID
THE ROCKS ON THE WAY



HEMLIBRA INJECTIONS
ARE GIVEN UNDER THE
SKIN. DON'T WORRY,
IT WAS DIFFERENT
AT FIRST BUT I
GOT USED TO IT

Hemlibra injections

- ↓ Hemlibra is given by an injection under the skin. This is called a **subcutaneous injection**
- 👤 This may be different to what you're used to. Your doctor or nurse will help you and the person who looks after you learn how to give subcutaneous injections
- 📺 There is a video that might also help. Scan the QR code below, or visit www.takingemicizumab.com



Hemlibra injections should be given at an angle of between 45° and 90° to the skin








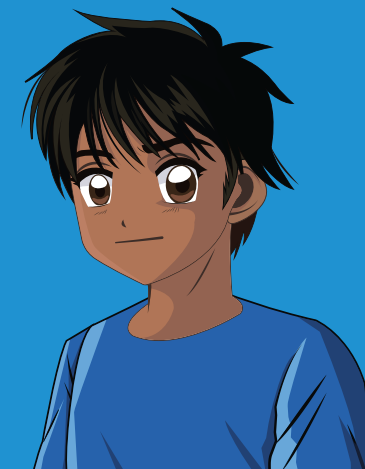


READY?

TAKE YOUR TIME AND
ASK FOR HELP IF
YOU'RE NOT SURE
ABOUT ANYTHING

Preparing for Hemlibra injections

-  Make sure you (or the person giving the injection) wash your hands well with soap and water before preparing and injecting Hemlibra
-  Take the Hemlibra out of the fridge and remove from the box. Check the expiry date and check the liquid in the vial is clear and colourless or slightly yellow. Do not use the vial if the liquid is cloudy, hazy, discoloured or contains any visible particles. Ask an adult to help you if necessary
-  Before using it, allow the vial(s) to reach room temperature for about 15 minutes on a clean flat surface away from direct sunlight
-  For each injection, choose a different area of the body to the one you used last time. Each injection should be at least 2.5 cm away from the area you used for your last injection. This also applies if your dose is given with more than one subcutaneous injection of Hemlibra
-  Clean the chosen area using an alcohol wipe and let the skin dry for about 10 seconds



HEY!

CAN YOU HELP ME
FIND HEMLIBRA?
IT'S HIDDEN AMONG
SOME OTHER
CLOTTING FACTORS
OVER THERE...



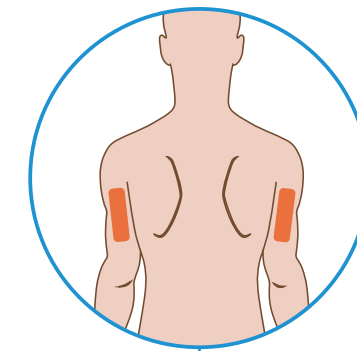
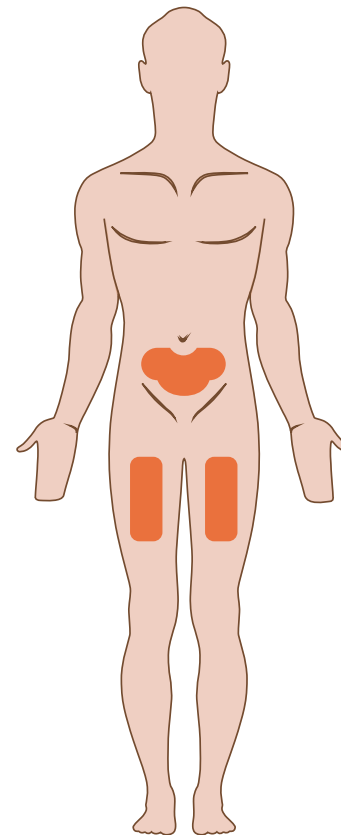
REMEMBER!

WASH YOUR HANDS,
CLEAN YOUR SKIN AND
CHANGE THE AREA
OF YOUR INJECTION
EACH TIME

Where to inject Hemlibra

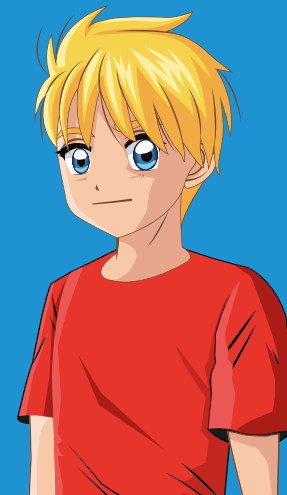
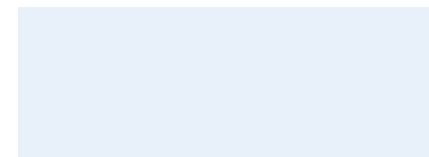
Hemlibra injections should only be given into certain parts of your body:

- Your thigh (front and middle)
 - Your stomach area, except for 5 cm around the belly button
 - The outer area of your upper arm (only if someone else is giving the injection)
- ! 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
- 📍 You can find more information about injecting Hemlibra on page 26, in the instructions in the Hemlibra package leaflet contained in the box with your medicine and the guide for patients/carers. A reminder video is available online at www.takingemicizumab.com.



caregiver only

Who can help with giving
your injections?



LOOK!

THIS PICTURE SHOWS
THE AREAS OF MY
BODY WHERE I CAN
HAVE MY HEMLIBRA
INJECTIONS

What side effects might I get with Hemlibra?

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

Very common: may affect more than 1 in 10 people

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

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

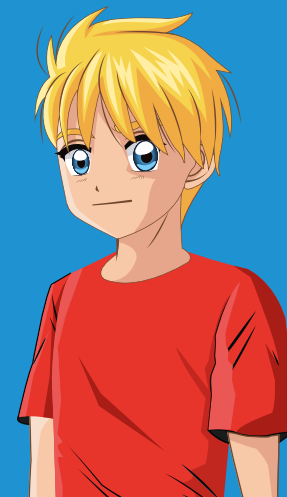
- Destruction of red blood cells (thrombotic microangiopathy)
- Blood clot in a vein behind your eye (cavernous sinus thrombosis)
- Severe damage of the skin tissue (skin necrosis)
- Blood clot in a vein near the surface of the skin (superficial thrombophlebitis)
- Lack of effect or decreased response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

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 or your caregiver notices 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. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. 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.








REMEMBER

ALL MEDICINES CAN CAUSE SIDE EFFECTS. TALK TO YOUR DOCTOR OR NURSE IF YOU FEEL POORLY AFTER TAKING YOUR HEMLIBRA



What happens if I have a bleed?

If you have a bleed, DO NOT take extra Hemlibra!

-  It is very important you and your caregiver talk to your doctor about what to do if you have a bleed when you are taking Hemlibra
-  You might need to take factor VIII replacement therapy. Hemlibra increases the ability of your blood to clot. Therefore, if you have used factor VIII replacement therapy to treat a bleed before, it may be different this time
-  Make sure you have your emergency plan before you start taking Hemlibra
-  If you need to see a doctor or nurse, make sure that you take your alert card with you
-  If you are using HealthID or have a MedicAlert bracelet or necklace, you should update your information

In an emergency:

Ask your doctor or nurse to write down what to do if you have a bleed.
(Remember to keep this updated, if anything changes).

Signed: _____

Emergency contacts:

Some additional questions you may have

Injecting Hemlibra

Who should I tell if I am having trouble with my injections?

Once you or the person who looks after you has been trained, you should be able to inject Hemlibra at home, by yourself or with their help. Tell your doctor or nurse if you are not confident with performing subcutaneous injections.

What if the Hemlibra vial or liquid looks strange?

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. 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 the next time you attend your centre.

I'm having trouble getting Hemlibra into the syringe

Hemlibra is quite a thick liquid. If you are performing your own injections, at first you might find it difficult to get it into the syringe. Talk to your doctor, nurse or the person who looks after you and they can help you if you are struggling.

Once I have transferred Hemlibra into a syringe, can I take it later?

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

How should I throw away my needles and syringes?

Any used vials, needles, vial/injection needle caps and used syringes should be placed in a sharps bin. Make sure that you use new needles and syringes for each injection and dispose of them after a single use.

If I do not use all the Hemlibra in a vial can I save it for the next injection?

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

Where I inject my Hemlibra is sore afterwards, what should I do?

This is a very common side effect that some people get with Hemlibra. Make sure that you change the area that you are using after each injection. If you have signs of redness, itching or soreness tell your doctor or nurse.

Some additional questions you may have

Taking Hemlibra

Should I tell people I have started taking Hemlibra?

Your regular haemophilia team, including your nurse and GP, will be told when you change medications. If you are using HealthID or have a MedicAlert bracelet or necklace, remember to update your details. It is up to you whether you want to tell your friends, family or a teacher about your treatment, but it may help to talk to people that are close to you so they can support you.

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 doctor or nurse are happy with how your treatment is going. Some people have taken Hemlibra for over five years.

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

No, If you think that you are having a bleed, do not take extra Hemlibra. The person who looks after you might take you to see your doctor or nurse about your pain.

If I have not had a bleed in a while, can I stop Hemlibra?

Even though it is good news that you have not had a bleed in a while, you still need to keep taking Hemlibra so you have a better chance of continuing to prevent bleeds in the future. Do not stop taking Hemlibra without talking to your doctor or nurse.

Can I have a break from taking Hemlibra?

Make sure you do not stop taking Hemlibra without talking to your doctor or nurse.

Are there any 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. If you have been taking factor VIII regularly to prevent bleeds, you might continue this for up to 7 days after starting Hemlibra.

Unlike you, some people who take Hemlibra have inhibitors to factor VIII (ask your doctor or nurse to explain this if necessary). They might use different treatments called bypassing agents to help manage their haemophilia A. Bypassing agents must be stopped the day before starting Hemlibra. One bypassing agent, called activated prothrombin complex concentrate (aPCC), should be avoided unless no other treatment option is available. This is because it has been shown to interact with Hemlibra, which can cause serious side effects. The package leaflet contained in the box with your medicine, the guide for patients/carers and patient alert card all include additional information. **Remember – you do not have inhibitors to factor VIII so it is very unlikely you will need to use bypassing agents.**

I forgot to take my Hemlibra, what do I do?

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.

Some additional questions you may have

Storing Hemlibra

How do I store Hemlibra at home?
Hemlibra needs to stay pretty cool – store your Hemlibra vials in your fridge (2°C to 8°C) in the original box. Do not freeze Hemlibra and do not shake the vials. Remember to check the expiry date written on the side of the box and on the vial label (the date refers to the last day of the month).

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 that has been in temperatures above 30°C.

Can I travel with Hemlibra?
Good news! Hemlibra can remain out of the fridge for up to 7 days, but you should store your Hemlibra vials in a fridge if 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. If you are travelling by aeroplane, talk to your doctor or nurse as they may give you 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 that they are not damaged during the flight. Remember, you may need to also carry factor VIII replacement therapy. Check with your doctor or nurse on how to carry this.

Lifestyle

Should I take more Hemlibra if I am going to play sport?
No. You must only take Hemlibra as prophylaxis regularly, as your doctor or nurse told you to. When Hemlibra was tested, people had stable levels of Hemlibra in their blood for the whole time between injections.

Should I take some factor VIII before playing sport?
No. If you were previously treating your severe haemophilia A with factor VIII you might be used to taking more before playing sport. Now you are taking Hemlibra this is not necessary.

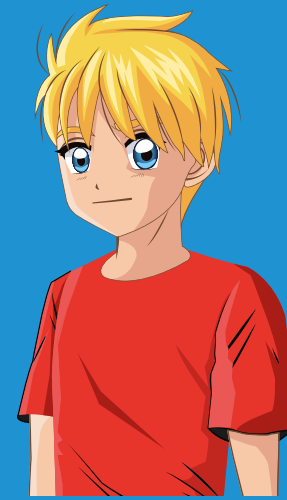
What activities are OK to do?
When you have haemophilia A, it's really helpful to stay active when you can. When taking Hemlibra, you can carry on with the hobbies and sports that you usually enjoy. Talk to your doctor or nurse first if you want to try any new activities.¹

Do I need to change what I eat?
You do not need to change your diet when you are taking Hemlibra, but it is important for anyone with severe haemophilia A to try to be as healthy as possible; eat well and make sure you drink plenty of water. You can find lots of information about staying healthy with haemophilia A from places like The Haemophilia Society or the World Federation of Hemophilia.

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

Any other questions?

If you have any other questions about Hemlibra or haemophilia A, write them down here so you remember them when you next see your doctor or nurse.



REMEMBER!

IF YOU NEED
TREATMENT FOR
A BLEED, TELL THE
DOCTORS OR NURSES
THAT YOU ARE
TAKING HEMLIBRA



Glossary

Here is a list of some words that we talked about in this booklet and their meanings

Clotting

To stop a bleed, blood changes from a liquid into a gel in the area that is damaged, for example, a small cut in a vein. The clot blocks the hole to stop blood from leaking out

Clotting factors

In your blood you have many things called clotting factors that work together to help make your blood clot

Factor VIII

When you have haemophilia A you have low levels, or none, of this clotting factor in your blood

Factor VIII replacement therapy

A medicine that replaces the low or missing factor VIII in the blood of people with haemophilia A

Haemophilia A

A bleeding disorder where people are missing or have very little factor VIII. Haemophilia A can be described as mild, moderate or severe depending on how much factor VIII is in the blood

Prophylaxis

The regular use of a treatment to prevent illness. For people with haemophilia A, prophylaxis is intended to prevent bleeding from occurring or reduce the number of bleeds that you have

Subcutaneous injection

A way to give medicine that involves injecting a small amount just beneath the skin

SPECIAL THANKS GOTO...

JULIA SPIRES,
CLINICAL NURSE SPECIALIST, HAEMOPHILIA
COMPREHENSIVE CARE CENTRE,
GREAT ORMOND STREET HOSPITAL

SIMON FLETCHER,
LEAD RESEARCH NURSE, OXFORD
HAEMOPHILIA AND THROMBOSIS
CENTRE, CHURCHILL HOSPITAL

LARA OYESIKU,
SOUTHERN HAEMOPHILIA NETWORK
CLINICAL NURSE MANAGER, HAMPSHIRE
HOSPITALS NHS FOUNDATION TRUST

SHARON THIND,
SPECIALIST PRACTITIONER, HAEMATOLOGY,
ALDERHAY CHILDREN'S HOSPITAL,
LIVERPOOL

**FOR THEIR HELP AND GUIDANCE DURING
THE DEVELOPMENT OF THIS BOOKLET**

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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. 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.