YOUR TREATMENT WITH HEMLIBRA®

CONDENSED INFORMATION IN ENGLISH

AVAILABLE IN DIFFERENT LANGUAGES.

ABOUT HEMLIBRA® FROM P. 03
USE OF HEMLIBRA® FROM P. 04
STORAGE OF HEMLIBRA® FROM P. 10
SPECIFIC ISSUES IN THE USE OF HEMLIBRA® FROM P. 11
HEMLIBRA® INJECTION INSTRUCTIONS FROM P. 13

YOUR TREATMENT WITH HEMLIBRA®

KEY QUESTIONS AND ANSWERS

Dear patient,

Your doctor has prescribed HEMLIBRA® for you. HEMLIBRA® is a medicine for the routine prevention of bleeding events. It is given to people who have moderate* and severe haemophilia A, and to everyone with haemophilia A who develops inhibitors. “Your treatment with HEMLIBRA® – Key questions and answers” provides you with detailed information concerning treatment with HEMLIBRA®

We wish you all the best!

* with severe bleeding phenotype

WHAT IS HEMLIBRA®?

HEMLIBRA® is a medicine for the routine prevention of bleeding events. It is given to people who have moderate* and severe haemophilia A, and to everyone with haemophilia A who develops inhibitors. HEMLIBRA® can be used in all age groups.

In patients with congenital blood clotting disorders, normal blood clotting cannot take place. This is either because their bodies produce too little blood coagulation factor (Factor VIII) or none at all, or because their bodies’ own immune systems form inhibitors that act against Factor VIII.

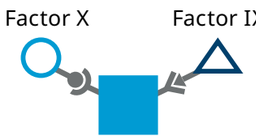
HEMLIBRA® cannot be used to treat acute bleeding events.

HOW DOES HEMLIBRA®WORK?

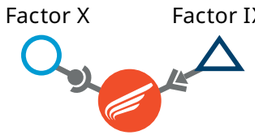
HEMLIBRA®contains an active substance called emicizumab. Emicizumab can take over the **function of Factor VIII**. The antibody mediates in the clotting cascade between Factor X and Factor IXa, and thus ensures that blood clotting works in the absence of Factor VIII. In this way, Hemlibra® mimics the action of Factor VIII. This is why Hemlibra® is also known as a Factor VIII mimetic.

Emicizumab also has another specific feature: HEMLIBRA® is not a factor replacement therapy. This means that the function of HEMLIBRA® is unaffected by the presence of inhibitors against Factor VIII. HEMLIBRA® can therefore be used in people with haemophilia A with inhibitors, as well as in people with moderate* and severe haemophilia A without inhibitors.

* with severe bleeding phenotype



1 FUNCTION OF FACTOR VIII

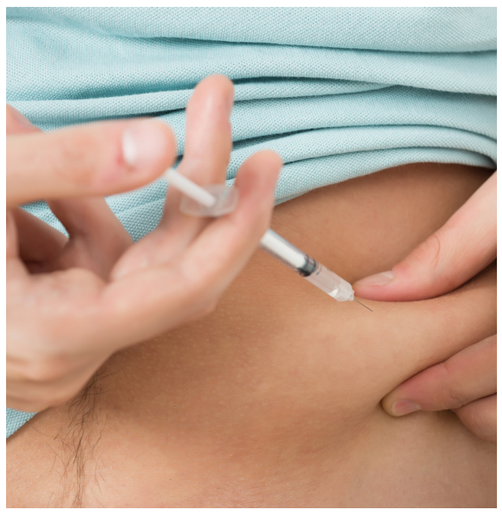


2 HEMLIBRA® COMPENSATES FOR MISSING FACTOR VIII

HOW IS HEMLIBRA® USED?

HEMLIBRA® is a ready-to-use solution. It is injected under the skin (subcutaneously). Your doctor or healthcare professional will provide you with appropriate training to enable you (or a carer) to perform the injection at home.

Please note: HEMLIBRA® is used to prevent bleeding and to reduce the number of bleeding events. This medicine is not used to treat an acute bleeding event.



WHAT DO I NEED TO BEAR IN MIND WHEN USING HEMLIBRA®?

Always write down the batch number of the HEMLIBRA® vials you are currently using, for example in your HEMLIBRA® treatment diary.

Only use each vial once, and dispose of it together with the remainder of the medicine.

Before starting treatment with HEMLIBRA®, discuss with your doctor what medications you may use for treating acute bleeding events while receiving treatment with HEMLIBRA®. Only ever use these and HEMLIBRA® exactly as agreed with your doctor.

Do you have further questions about using HEMLIBRA®? Consult your doctor or healthcare professional.

WHAT IS THE DOSAGE FOR HEMLIBRA®?

The doctor who is treating you will set the dose that is suitable for you, and will calculate the quantity of HEMLIBRA® solution that you will need to inject. Always adhere exactly to the dose prescribed by your doctor. You will receive a weekly **initial dose** for the first four weeks of your treatment with HEMLIBRA®, then a **maintenance dose from the fifth week onwards.**

INITIAL DOSE WEEKS 1–4

3 mg per kg body weight

MAINTENANCE DOSE AS FROM WEEK 5

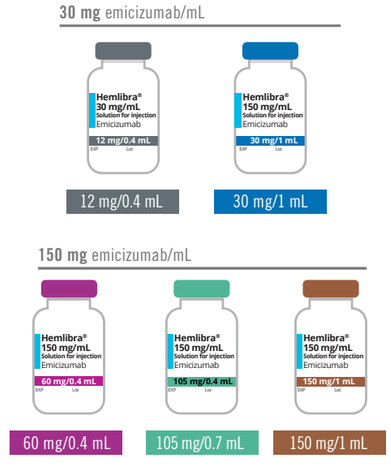
1.5 mg per kg body weight WEEKLY
or
3 MG PER KG BODY WEIGHT EVERY TWO WEEKS
or
6 mg per kg body weight EVERY FOUR WEEKS

WHAT ARE THE AVAILABLE CONCENTRATIONS AND SIZES OF HEMLIBRA®?

HEMLIBRA® is available in the following concentrations:

Different concentrations of HEMLIBRA®(30 mg/mL and 150 mg/mL) must not be combined in the same syringe when preparing the total volume for use. The doctor who is treating you will set the dose that is suitable for you, and will calculate the quantity of HEMLIBRA® solution that you will need to inject for this. If your prescribed dose is more than 2 millilitres (mL), you will need more than one injection. Discuss the procedure with your doctor.

HEMLIBRA® is supplied in vials for single use as a ready-to-use solution. Opened vials must not be reused.

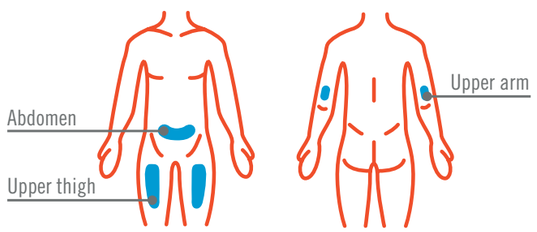


WHICH BODY LOCATIONS ARE SUITABLE FOR THE INJECTION OF HEMLIBRA®?

HEMLIBRA® can be injected under the skin (subcutaneously) at various locations on the body.

If you are injecting yourself with HEMLIBRA®, the front of your thighs and your abdomen are suitable. However, keep at least 5 centimetres away from your navel.

Important: You should use a different injection site every time; this can prevent or reduce reactions at the injection site. Maintain a distance of at least 2.5 centimetres from the previous injection site.



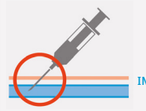
The subcutaneous injection should not be given in areas where the skin is reddened, injured, sensitive, scarred or hardened, or where there are moles. You should also avoid areas that could be irritated by clothing, such as a trouser waistband.

If you are not administering HEMLIBRA® to yourself but to another trained person, the outer sides of the upper arms are also suitable for injection.

EMICIZUMAB

- Injected under the skin (subcutaneously) into fatty tissue
- Only for prevention of bleeding
- Used once a week, fortnightly or every 4 weeks

FACTOR VIII PREPARATION



- Must be injected into the vein
- For the prevention and treatment of bleeding events
- Use for prevention 1 to 3 times a week
- For bleeding events up to twice a day

WHAT SHOULD I BEAR IN MIND AFTER THE INJECTION?

If you notice a drop of blood at the injection site after injecting HEMLIBRA®, press a sterile wound dressing onto it. Maintain pressure for 10 seconds, or until no more blood appears.

Do not rub the injection site, even if it starts to itch.

If you discover bleeding under the surface of the skin at the injection site, it is advisable to press an ice pack on to the affected area to stop the bleeding.

If bleeding does not stop despite these actions, contact your doctor immediately.

WHAT SHOULD I DO IF I HAVE FORGOTTEN AN INJECTION OF 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 continue with the injections according to the dosage schedule. Do not take two doses on the same day if you have forgotten the previous injection.

If you are not sure what to do, consult your doctor or healthcare professional.

WHAT SHOULD I DO IF I HAVE ADMINISTERED TOO MUCH ACTIVE INGREDIENT?

If you or your carer have used more HEMLIBRA® than prescribed, contact your doctor immediately.

Always use HEMLIBRA® exactly as agreed. If you have any questions about dosage or use, please do not hesitate to ask your doctor or healthcare professional.

2 CREATE HEMLIBRA® CALENDAR ENTRY

HOW CAN I HELP MYSELF NOT TO FORGET HEMLIBRA® TREATMENT?

Keeping a regular HEMLIBRA® treatment diary will help you to ensure that you never miss an injection.

Friends or family may also be able to help you to remember. Or you can simply use your mobile phone, and set yourself a weekly, fortnightly or four-weekly reminder.

CAN HEMLIBRA® ALSO BE USED TO TREAT ACUTE BLEEDING EVENTS?

HEMLIBRA® is only suitable for preventative treatment, not for the treatment of bleeding events. It is therefore very important that before starting treatment with HEMLIBRA®, you discuss with your doctor when, and at what dosages, you can take medications for the treatment of acute bleeding events while you are using HEMLIBRA®. For patients with inhibitors, such medications are called bypassing agents. Adhere strictly to the instructions from your doctor. The following points should be borne in mind when using HEMLIBRA® and bypassing medications at the same time:

- You should end treatment with preventative bypassing agents the day before starting treatment with HEMLIBRA®.
- HEMLIBRA® increases the clotting potential of your blood. It is therefore possible that if you experience a bleeding event, the required dose of bypassing agent will be lower than before you received treatment with HEMLIBRA®, or that no additional bypassing agent will be required. The dose and duration of use of the bypassing agent will depend on the site and extent of the bleeding. Please discuss this with your doctor.
- Bypassing agents include activated prothrombin complex concentrate (aPCC) and recombinant factor VIIa (rFVIIa). Serious and potentially life-threatening side effects have been observed when aPCC is used in patients who have also received HEMLIBRA®.
- The use of aPCC should be avoided unless no other treatment options/alternatives are available.

WHAT INFORMATION DO THE DOCTORS TREATING ME NEED?

Inform your doctors and healthcare professionals that you are using HEMLIBRA® to treat your haemophilia A.

Tell your doctor and healthcare professional that you are using HEMLIBRA® before you undergo laboratory tests to determine your blood clotting. Some laboratory tests are affected by HEMLIBRA® and therefore provide false results. These tests are known in specialist language as "coagulation tests", "clotting-based tests" or "inhibitor tests".

The digital emergency passport, which you can download from HEMCOACH.DE, will help you with this.

WHAT MUST BE DONE IN AN EMERGENCY?

In an emergency, contact a doctor for immediate medical care.

The medical staff may have questions about your illness or your current treatment as a result of the emergency. If possible, make sure that you have the name and, if possible, contact details of your haemophilia treatment provider to hand.

HOW MUST HEMLIBRA® BE STORED?

Always keep HEMLIBRA® in its original packaging. It is also important to keep HEMLIBRA® protected from light and refrigerated.

HEMLIBRA® must be stored in a refrigerator at a temperature between 2°C and 8°C. However, remember always to remove the vial(s) from the refrigerator 15 minutes before injection, so that the medication reaches room temperature before use.

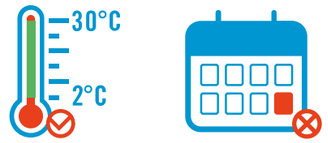
HEMLIBRA® must not be frozen or shaken. Once you have drawn HEMLIBRA® into a syringe, you must either use it or dispose of it.

You can store HEMLIBRA® unopened at room temperature for up to 7 days. You can therefore store HEMLIBRA® at room temperature for 2 days, put it back in the refrigerator, and later leave it unrefrigerated for another 5 days – and still use the medicine as long as the bottle is unopened. The total period during which the medication is not refrigerated must not exceed 7 days. The storage temperature must also never exceed 30°C.

WHEN SHOULD A HEMLIBRA® VIAL NO LONGER BE USED?

HEMLIBRA® must no longer be used in the following circumstances:

- The expiry date has passed (2-year shelf life).
- The medication is cloudy or no longer colourless.
- Small particles can be seen in the liquid.
- The cap is missing or the vial appears to be damaged in some other way.
- The vial has been exposed to temperatures above 30°C or below 2°C, or has been left unrefrigerated for a total of more than 7 days.



WHAT SIDE EFFECTS CAN OCCUR DURING TREATMENT WITH HEMLIBRA®?

As with all medicines, side effects can occur with HEMLIBRA® treatment, but not every patient will experience them.

The following side effects may occur very frequently, i.e. in more than 1 in 10 people treated:
- Reactions at the injection site: redness, itching or pain at the puncture site
- Headache
- Joint pain

The following side effects may occur frequently, i.e. in up to 1 in 10 people treated:
- Fever
- Muscle pain
- Diarrhoea
- Itchy rash or hives (nettle rash)
- Skin rash

The following side effects may occur occasionally, i.e. in up to 1 in 100 people treated:
- Blood clot in a vein behind the 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)
- Destruction of red blood cells (thrombotic microangiopathy)
- Indication of angio-oedema: facial swelling, swollen tongue and/or swollen throat and/or difficulty swallowing, or wheals, in conjunction with breathing difficulties
- Lack of effect or decreased response to treatment

This does not mean that you will also experience these side effects. However, if you notice the first signs of these or other side effects, contact your doctor immediately.

ARE THERE ANY INTERACTIONS WITH OTHER MEDICATIONS?

Tell your doctor if you are using, have used or intend to use any other medicines.

The simultaneous use of Hemlibra® and FEIBA®(aPCC) should be avoided. The following serious side effects may occur:

Destruction of red blood cells (thrombotic microangiopathy):
In this serious condition, the inner wall of the blood vessels is damaged. This can cause blood clots to form in small blood vessels, which in turn can damage organs.
- Symptoms may include confusion, weakness, swelling of the arms and legs, yellowing of the skin and eyes, vague abdominal or back pain, nausea, vomiting or reduced urination.

Blood clot formation (thromboembolism):
in rare cases, blood clots can cause a life-threatening blockage of blood vessels.
- Blood clot in a vein, close to the surface of the skin: possible symptoms may include swelling, warmth, pain or redness.
- Blood clot in a vein behind the eye: possible symptoms may include headaches, numbness in the face, eye pain or swelling, or visual disturbances
- Severe skin tissue damage: black discolouration of the skin may occur as a possible symptom.

If you notice any signs of these side effects, stop using HEMLIBRA® and FEIBA® (aPCC) immediately and consult your doctor without delay.

HEMLIBRA® has no or negligible influence on the ability to drive and use machines.

WHAT DO I NEED TO THINK ABOUT BEFORE TRAVELLING?

Certificates:
Before travelling, make sure you have the necessary documents. Depending on where you are travelling to, you may, for example, need a customs certificate and a medical certificate to import your medication into a country or take it with you on the plane. You can order and/or download the customs certificate from HEMCOACH.DE.

Dose:
Before travelling, consider how many HEMLIBRA® Don't forget to plan extra vials in case of the unexpected, and make sure you pack enough injection equipment.

Cooling:
HEMLIBRA® may only be stored unrefrigerated for up to 7 days. You will therefore need to ensure that you can keep the medication cool where you are going.

Air travel:
Carry your medication in your hand luggage so that it does not get lost with your suitcase or exposed to cold temperatures. Remember that HEMLIBRA® must not be stored above 30°C and must not be kept unrefrigerated for longer than 7 days in total. It is therefore advisable to refrigerate HEMLIBRA® when travelling if you are going to be away for a long time or if you may need to store the medication again later without refrigeration. You may also carry injection equipment, including needles and syringes, in your hand luggage with a medical certificate.

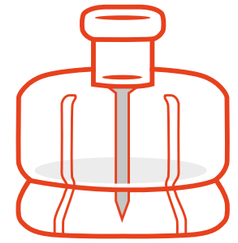
WHAT MUST I THINK ABOUT BEFORE MEDICAL PROCEDURES AND OPERATIONS?

Before medical procedures and operations, it is best to discuss what needs to be done with the doctor treating you. He/she can tell you what you need to think about, and whether, and if so when, you should take additional medication.

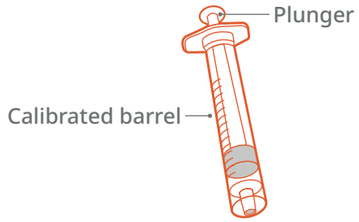
HEMLIBRA® INJECTION INSTRUCTIONS

REQUIRED INJECTION ACCESSORIES

HEMLIBRA® vial(s) and instructions for use

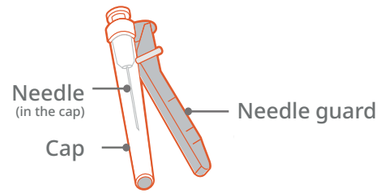


Adapter with filter* (for attaching to the vial)
Used to transfer the medicine from the vial to the syringe. Do not insert the injection needle into the adapter.



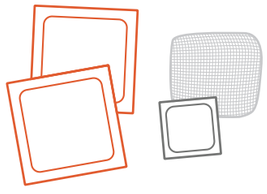
Syringe

For injections of up to 1 mL of solution, use a 1 mL disposable syringe; for injections of more than 1 mL and up to 2 mL, use a 2 mL disposable syringe.



Injection needle

Do not use the injection needle to draw up the medicine.



Alcohol swabs, gauzes, plasters (not included in the injection kit)

Use a new alcohol swab for each vial.

Puncture-resistant needle collection box for disposal

INJECTION KIT FOR THE ADMINISTRATION OF HEMLIBRA®

The injection kit contains the necessary utensils for injecting HEMLIBRA®. Your treating doctor can order the injection kit for you free of charge from Roche.

INJECTION ACCESSORIES FOR THE ADMINISTRATION OF HEMLIBRA®

The injection accessories (alcohol swabs, gauzes and plasters) can be ordered free of charge from HEMCOACH.DE.

***referred to after this as the adapter**

FOR THE ADMINISTRATION OF HEMLIBRA®

Read these injection instructions carefully before injecting HEMLIBRA®. Follow all instructions included with the injection.

Before you use HEMLIBRA® for the first time, your doctor or healthcare professional will show you the preparations you need to make, the correct dosage and the appropriate injection technique.

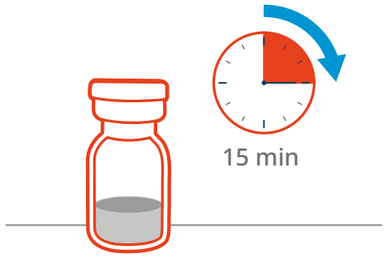
Consult your doctor or healthcare professional if you have any questions.

!

IMPORTANT INFORMATION

- Use each vial only once: after injection, dispose of the remaining HEMLIBRA® solution with the vial. Do not keep any leftover medicine for later use.
- Only use syringes and injection needles that your doctor has prescribed.
- Syringes, adapters and injection needles may only be used once.
- Do not use the injection needle to draw up the medicine from the vial.
- Dispose of all used syringes and needles properly.
- Further information on the storage and use of HEMLIBRA® can be found in "Your treatment with HEMLIBRA® – Key questions and answers" and on WWW.HEMCOACH.DE.

EVERYTHING READY?



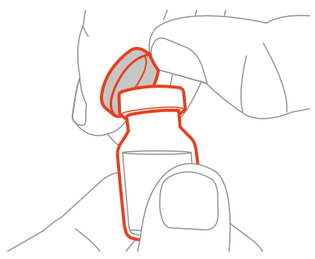
!

Start injection preparations:
15 minutes before the injection.

Take the vial(s) you need out of the refrigerator and make sure that HEMLIBRA® is printed on the outer cartons and the labels. Check the concentrations and expiry dates on all vials. Place all the required vials on a clean surface out of direct sunlight for 15 minutes. Get the injection accessories ready.

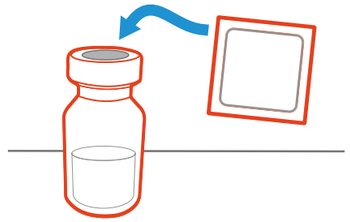
1

Wash your hands thoroughly with soap and water.



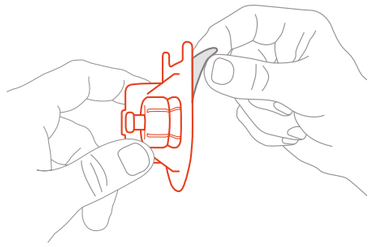
2

Remove the cap(s) from the vial(s) and dispose of them in your needle collection box.



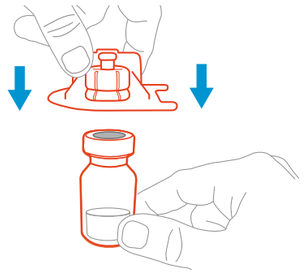
3

Wipe the surface of the rubber stopper with a new alcohol swab each time.



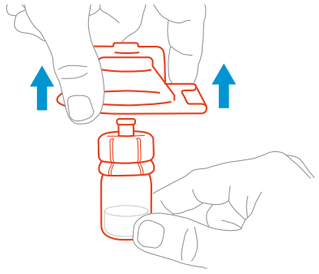
4

To open the blister pack of the adapter, pull off the back. – Do not remove the adapter from the transparent plastic blister pack.



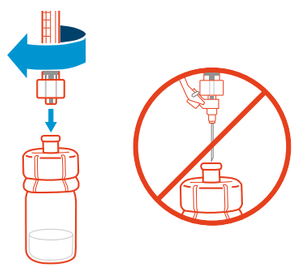
5

To attach the adapter to the vial, press the plastic blister pack with the adapter in it firmly on to the new vial until you hear a click.



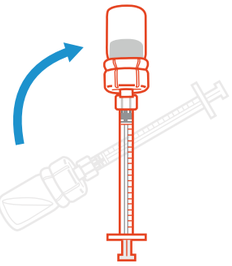
6

Remove the plastic blister pack and dispose of it. Do not touch the tip of the adapter.



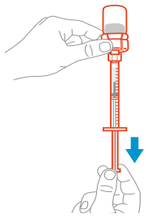
7

Remove the cap from the syringe (if necessary). Press and turn the syringe clockwise on to the adapter until it engages fully.



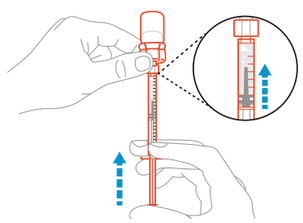
8

Hold the adapter on the syringe and turn the vial upside down.



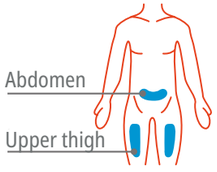
9

With the syringe pointing upwards, slowly pull back the plunger and fill the syringe with the injection solution. Make sure that the amount of medicine is slightly larger than your prescribed dose. Hold the plunger firmly to ensure that it cannot slip back. Take care not to pull the plunger out of the syringe.



10

Leave the vial attached to the syringe and check the syringe for any large air bubbles. If there are large air bubbles, the dose administered may be too low. Remove larger air bubbles by gently tapping the syringe barrel with your finger until the air bubbles in the syringe rise to the top. Slowly push the plunger upwards to remove the large air bubbles from the syringe.



11

Clean the chosen injection site using an alcohol swab. Then allow the skin to dry for 10 seconds. Do not touch the cleaned area again before the injection.

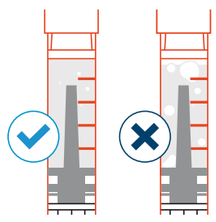
You can inject into the following locations on the body:

- Upper thigh (front and centre)
- Abdomen, except 5 cm around the navel
- Outer side of the upper arms (only if a carer administers the injection)

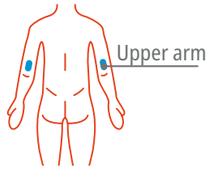
!

USING MULTIPLE VIALS

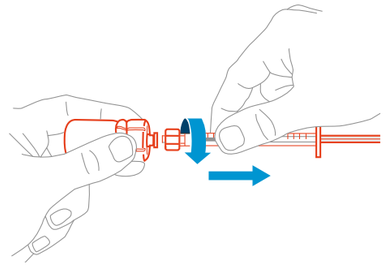
If your prescribed dose is larger than the amount of medicine in the vial, draw up the entire injection solution. Then simply go to the section **“Combining vials”** and continue as described there.



If the syringe now contains exactly the prescribed dose of medicine or less, slowly pull out the plunger until there is more medicine in the syringe than you need for your prescribed dose. Again, ensure that you do not pull the plunger completely out of the syringe. Repeat the steps described above until all large air bubbles have been removed.

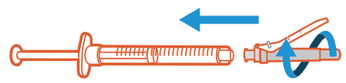


Change the injection site for each injection. Maintain a distance of at least 2.5 cm from the previous injection site. Do not inject into areas that could be irritated by your clothing. Reddened, injured, sensitive or hardened areas of skin, as well as moles, scars or bruises are also unsuitable for injection.



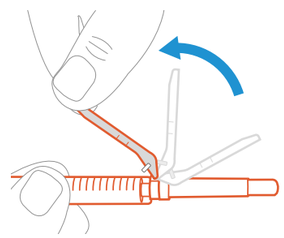
12

Now remove the syringe from the adapter by turning it anticlockwise and carefully pulling it off. Dispose of the used vial and the used adapter in a needle collection box.



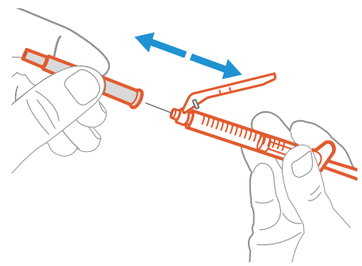
13

Place the injection needle on the syringe, press and turn it clockwise until it engages fully.



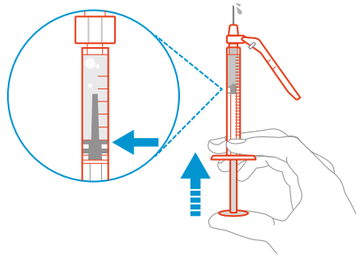
14

Move the needle guard away from the needle and toward the syringe barrel.



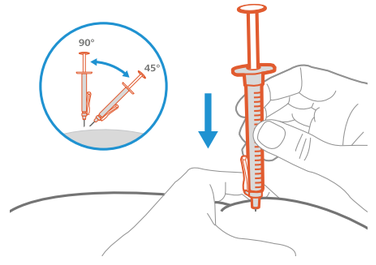
15

Remove the injection needle cap from the syringe and dispose of it in the needle collection box. Do not touch the needle tip and ensure that the tip does not come into contact with surfaces.
If the needle is bent or damaged, do not attempt to straighten it or to use the medicine.
Inject the injection fluid within the next 5 minutes.



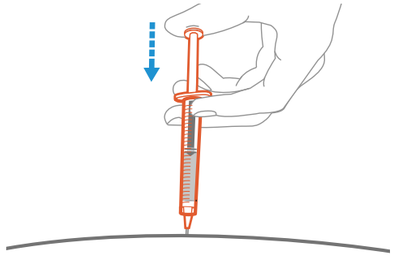
16

Hold the syringe with the needle pointing upwards and slowly press the plunger into the syringe until the correct dose is reached. The upper edge of the plunger must be exactly on the mark on the syringe corresponding to your dose.



17

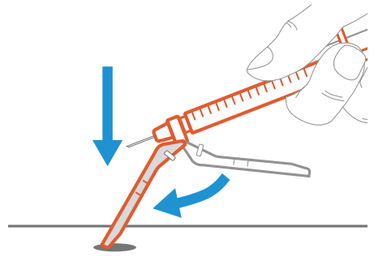
Pinch up a skin fold at the chosen injection site and quickly insert the needle completely at an angle of 45 to 90 degrees. Do not hold or push the plunger down while inserting the needle.



18

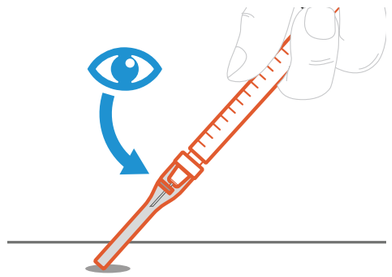
Hold the syringe in this position and let go of the pinched skin fold. Carefully press the plunger fully down, and slowly inject all the medicine.

Pull the needle and syringe out of the injection site at the same angle as you inserted them.



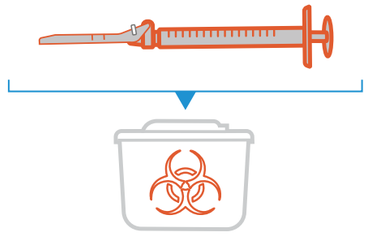
19

Fold the needle guard 90 degrees away from the syringe barrel and press the needle guard onto a flat surface until you hear a click.



20

If no click is heard, check that the needle is completely covered by the needle guard. Always keep your fingers behind the needle guard.



21

Do not remove the used injection needle from the syringe and do not replace the cap on the injection needle. Dispose of used needles and syringes directly in a needle collection box.

22

Enter the administration of the medicine in your treatment diary.

!

AFTER THE INJECTION

Do not rub the injection site after injection. If drops of blood appear at the injection site, press a sterile cotton pad onto the injection site until the bleeding has stopped. If a bruise forms, hold a cooling pad on the area, maintaining light pressure. If the bleeding does not stop, consult your doctor.

COMBINING VIALS

If you need more than one vial to administer your prescribed dose, carry out the following steps after you have drawn up the medicine from the first vial:

- To open the blister pack of the adapter, pull off the back.
- Do not remove the adapter from the transparent plastic blister pack.
- Press the plastic blister pack with the adapter in it firmly on to the new vial until you hear a "click".
- Remove the plastic blister pack and dispose of it.
- Do not touch the tip of the adapter.
- Remove the syringe from the adapter by turning it anticlockwise and carefully pulling it. Dispose of the used vial(s)/adapter(s) in a needle collection box.
- Press and turn the same syringe clockwise on to the next adapter until it engages fully.
- Hold the adapter on the syringe and turn the vial upside down.
- With the syringe pointing upwards, slowly pull back the plunger to draw up the required amount of medicine as described in point 9.
- Repeat these steps with each additional vial until there is more medicine in the syringe than your prescribed dose.
- Then continue with step 10.

!

IMPORTANT INFORMATION

You should fit a new adapter to the vial each time you take the medicine from a new vial. Vials of different concentrations must not be combined. Make sure that you do not use more than 2 mL per injection.

!

SPECIAL ISSUES FOR CHILDREN

As soon as your child is old enough, explain to them why the prick under the skin is necessary and that this is the only way to get the active ingredient to the right place. Exude calm before and during the injection, and distract your child from the injection. You might do this, for example, with an exciting story, music or a video.

Further information on HEMLIBRA® can be found at WWW.HEMCOACH.DE. In the login area you can also watch video instructions for injecting HEMLIBRA®.

FURTHER INFORMATION

Your first point of contact for questions, problems or uncertainties regarding your HEMLIBRA®treatment is always the doctor who is treating you. You can find more helpful information and materials at HEMCOACH.DE .

If you have any further questions about your HEMLIBRA® treatment, the Roche Patient Information Service staff are there for you. You can reach them by e-mail at: **grenzach.arzneimittel@roche.com** or from Monday to Friday between 9:00 a.m. and 6:00 p.m. on the telephone number: **07624 / 14-2015**

Roche Pharma Ltd
Patient Partnership Hemophilia
Emil-Barell-Strasse 1
79639 Grenzach-Wyhlen, Germany

Chugai Pharma Germany GmbH

Amelia-Mary-Earhart-Straße 11b
60549 Frankfurt, Germany

www.chugaipharma.de

© 2025

All brand names mentioned are protected by law.

www.roche.de

M-DE-00028120