



**YOUR
HEMLIBRA®
TREATMENT
IHRE THERAPIE
MIT HEMLIBRA®**

**COMPACT INFORMATION IN
ENGLISH**

**KOMPAKTE INFORMATIONEN
AUF ENGLISCH**



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Dear patient,

Your doctor has prescribed HEMLIBRA® to you. HEMLIBRA® is a medicine used for the routine prevention of bleeding episodes. It is used in people with moderate* and severe haemophilia A and in all people with haemophilia A with inhibitors. "My HEMLIBRA® treatment – The most important questions and answers" provides you with detailed information about therapy with HEMLIBRA®.

We wish you all the best!

* with severe bleeding phenotype

YOUR HEMLIBRA® TREATMENT

THE MOST IMPORTANT QUESTIONS AND ANSWERS



WHAT IS HEMLIBRA®?

HEMLIBRA® is a medicine used for the routine prevention of bleeding episodes. It is used in people with moderate* and severe haemophilia A and in all people with haemophilia A with inhibitors. Hemlibra can be used in all age groups.

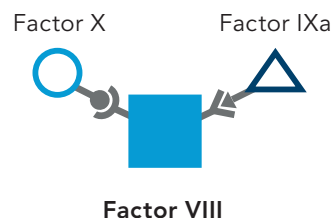
In patients with congenital coagulation disorders, normal blood clotting cannot take place. This is due to the fact that the body either produces too little or no coagulation factor (factor VIII) or that its own immune system forms inhibitors against factor VIII.

HEMLIBRA® cannot be used to treat acute bleeding.

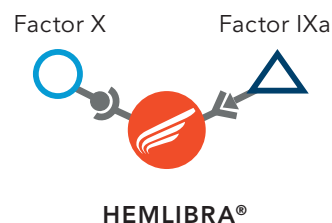
HOW DOES HEMLIBRA® WORK?

HEMLIBRA® contains the active substance emicizumab. Emicizumab can assume **the function of factor VIII**: The antibody mediates in the coagulation cascade between factor X and factor IXa, and thereby replaces the missing factor VIII to ensure effective blood clotting.

In addition, emicizumab has another important characteristic: HEMLIBRA® is not a factor replacement therapy. The function of HEMLIBRA® is therefore not affected by the presence of inhibitors against factor VIII. As a result, HEMLIBRA® may be used in people with haemophilia A with inhibitors, as well as in people with moderate* and severe haemophilia.



1 FACTOR VIII FUNCTION



2 HEMLIBRA® REPLACES THE MISSING FACTOR VIII

* with severe bleeding phenotype

HOW IS HEMLIBRA® USED?

HEMLIBRA® is a ready-to-use solution. It is injected under the skin (subcutaneously). Your doctor or another healthcare professional will train you (or a caregiver) to administer the injection at home.

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



WHAT SHOULD I BEAR IN MIND WHEN USING HEMLIBRA®?

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

Use each vial only once and discard it along with any unused medicine left in it.

Before starting treatment with HEMLIBRA®, discuss with your doctor which medications you may use for treating acute bleeding episodes while you are on HEMLIBRA®. Always use these medicines and HEMLIBRA® exactly as discussed with your doctor.

Do you have any further questions about how to use HEMLIBRA®? Contact your doctor or the healthcare professional

WHAT IS THE DOSE REGIMEN FOR HEMLIBRA® ?

You and the doctor treating you will decide together which dose is right for you and will calculate the amount of HEMLIBRA® solution you need to inject. Always take exactly the dose prescribed by your doctor. In the first four weeks of treatment with HEMLIBRA®, you will receive an **initial dose** weekly, followed by a **maintenance dose from the fifth week onwards**.

INITIAL DOSE 1st–4th WEEK

**3 mg
per kg body weight**

MAINTENANCE DOSE FROM THE 5th WEEK

**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**

IN WHAT CONCENTRATIONS AND SIZES IS HEMLIBRA® AVAILABLE?

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 the total volume for administration is being prepared. You and the doctor treating you will decide together which dose is right for you and calculate the amount of HEMLIBRA® solution you need to inject. If the dose prescribed to you is more than 2 millilitres (ml), you will need more than one injection. Talk with your doctor about how to do this.

HEMLIBRA® comes in single-use vials as a ready-to-use solution. Vials that are already open must not be reused.

30 mg HEMLIBRA®/ml



12 mg/0,4 ml

30 mg/1 ml

150 mg HEMLIBRA®/ml



60 mg/0,4 ml

105 mg/0,7 ml

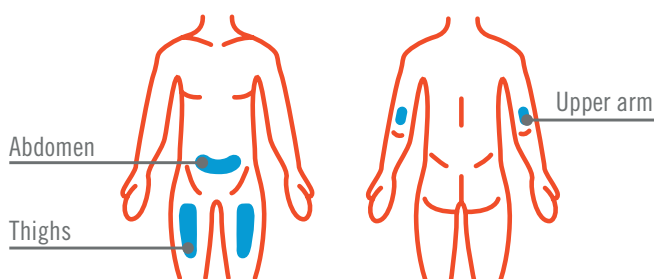
150 mg/1 ml

IN WHICH REGIONS OF THE BODY CAN I INJECT HEMLIBRA®?

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

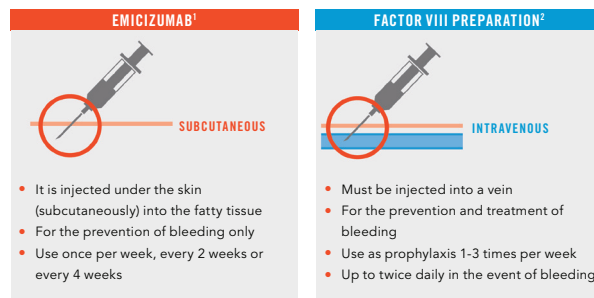
If you inject HEMLIBRA® yourself, the fronts of your thighs and your abdomen work well. However, do not inject within 5 centimetres of the navel (belly button).

Important: You should use a different injection site each time to prevent or reduce injection site reactions. The minimum distance from the previous injection site should be 2.5 cm.



Subcutaneous injection should not be placed in red, injured, sensitive, scarred or hard skin or into moles. Also avoid areas that could be irritated by clothing, such as the waistband.

If you are not injecting HEMLIBRA® yourself but have another trained person do so, the outer areas of the upper arms work well.



WHAT DO I NEED TO DO AFTER THE INJECTION?

If you notice a drop of blood at the injection site after the injection of HEMLIBRA®, press a sterile wound dressing on the injection site. Apply pressure for 10 seconds or until the bleeding stops.

Do not rub the injection site, even if it starts to itch. If you discover bleeding under the skin surface at the puncture site, we recommend that you apply an ice pack to the area to stop the bleeding.

If the bleeding does not stop despite these measures, contact the doctor treating you immediately.





WHAT SHOULD I DO IF I FORGET AN INJECTION OF HEMLIBRA®?

If you have forgotten the planned injection, take the missed dose as soon as possible before the day of the next planned dose. Continue with the injections in line with the dosing schedule. Do not use two doses on the same day if you have forgotten the previous dose.

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

WHAT SHOULD I DO IF I HAVE INJECTED TOO MUCH MEDICINE?

If you or your caregiver have injected more HEMLIBRA® than you should, contact your doctor immediately.

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



CREATE HEMLIBRA® CALENDAR ENTRY

WHAT CAN HELP ME TO REMEMBER TO TAKE HEMLIBRA® TREATMENT?

Regularly keeping a HEMLIBRA® treatment diary helps you prevent missed injections.

Maybe friends or family can also help remind you. Or simply use your mobile phone to set up a weekly, two-weekly or four-weekly reminder.

CAN HEMLIBRA® ALSO BE USED TO TREAT ACUTE BLEEDING?

HEMLIBRA® is for prophylaxis only and not for treating bleeding episodes. Before starting treatment with HEMLIBRA® it is therefore very important for you to talk to your doctor about when you may use medicines for the acute treatment of bleeding while you are on HEMLIBRA® treatment, and in what doses. In patients with inhibitors, these are called bypassing agents. Follow your doctor's instructions exactly. If you are using HEMLIBRA® and bypassing agents at the same time, please note the following:

- You should stop treatment with preventive bypassing agents the day before starting HEMLIBRA® treatment.
- HEMLIBRA® increases the potential for your blood to clot. Therefore in the case of bleeding, the required dose of the bypassing agent may be lower than before treatment with HEMLIBRA® or no additional bypassing agent might be required at all. The dose and duration of use of the bypassing agent depend on the site and extent of bleeding. Please discuss this with your doctor.
- Bypassing agents include activated prothrombin complex concentrate (aPCC) and recombinant activated factor VIIa (rFVIIa). Serious and potentially life-threatening side effects were observed when aPCC is used in patients who have also received HEMLIBRA®.
- You should not use aPCC unless there are no other treatment options/alternatives.



WHAT SHOULD I DO IN AN EMERGENCY?

In emergencies, see a doctor for immediate medical care.

During the emergency treatment, healthcare professionals may have questions about your disease or current treatment. If possible, provide the name and if possible contact details of your haemophilia treatment provider.

WHICH INFORMATION DO ATTENDING DOCTORS REQUIRE?

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

Inform your doctor and the medical staff that you are using HEMLIBRA® before lab tests are carried out on you to determine your blood clotting. Some laboratory tests are affected by HEMLIBRA® and therefore provide incorrect results. In technical language, these tests are called "coagulation", "clotting" or "inhibitor" tests.

The digital emergency passport, which can be downloaded from [HEMCOACH.DE](https://hemcoach.de), is available to support you.

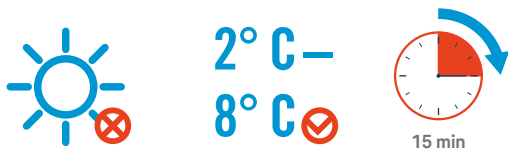


HOW SHOULD HEMLIBRA® BE STORED?

Always store HEMLIBRA® in its original packaging. It is also important to keep HEMLIBRA® protected from light and in a cool environment.

HEMLIBRA® must be stored in the refrigerator at 2°C to 8°C. Remember to always take the vial(s) out of the refrigerator 15 minutes before the injection so that the medicine warms up to room temperature before use.

HEMLIBRA® must not be frozen or shaken. Any HEMLIBRA® that has been drawn up into a syringe, must be either used or discarded.

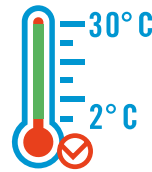


You can store unopened vials of HEMLIBRA® at room temperature for up to seven days. This means you can store HEMLIBRA® at room temperature for two days, put it back in the refrigerator, then keep it at room temperature again for five days – and still use the medicine as long as the vial is unopened. The total time in which the medication is not refrigerated should not exceed 7 days. In addition, the temperature must never exceed 30°C.

UNDER WHICH CONDITIONS SHOULD I NO LONGER USE A HEMLIBRA® VIAL?

Do not use HEMLIBRA® vials in the following cases:

- The expiry date has been exceeded (2- year shelf life).
- The medication is cloudy or no longer colourless.
- Small particles can be seen in the fluid.
- The lid is missing or the vial appears otherwise damaged.
- The vial was exposed to temperatures above 30°C or below 2°C, or was stored outside the refrigerator for a total of more than 7 days.



WHICH SIDE EFFECTS MAY ARISE DURING HEMLIBRA® TREATMENT?

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

The following side effects are very common, meaning they may affect more than 1 in 10 people:

- Injection-site reactions: Redness, itching or pain at the injection site
- Headache
- Joint pain

The following side effects are common, meaning they may affect up to 1 in 10 people:

- Fever
- Muscle aches
- Diarrhoea
- Itchy rash or wheals (hives)
- Rash

The following side effects are uncommon, meaning they may affect up to 1 in 100 people:

- Blood clot in a vein behind your eye (sinus cavernosus thrombosis)
- Severe damage to the skin tissue (skin necrosis)
- Blood clot in a vein near the surface of the skin (superficial thrombophlebitis)
- Blood and lymph system disorders
- Destruction of red blood cells (thrombotic microangiopathy)
- Indication of angio-oedema: swollen face, swollen tongue and/or swollen throat and/or difficulty swallowing, or hives, in combination with difficulty breathing
- Lack of effect or decreased response to treatment

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

ARE THERE INTERACTIONS WITH OTHER MEDICINES?

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

The simultaneous use of HEMLIBRA® and FEIBA® (aPCC) may cause the following serious side effects:

Destruction of red blood cells (thrombotic microangiopathy):

In this serious condition, the inside wall of blood vessels is damaged. This can cause blood clots to form in small blood vessels, which can, in turn, damage the organs.

- Symptoms may include confusion, weakness, swelling of the arms and legs, yellowing of skin and eyes, general abdominal or back pain, nausea, vomiting or decreased urination.

Blood clot formation (thromboembolism):

In rare cases, blood clots can cause life-threatening obstruction of blood vessels.

- Blood clots in a vein, near the surface of the skin: Symptoms may include swelling, warmth, pain, or redness.
- Blood clots in a vein behind the eye: Possible symptoms may include headache, numbness in the face, eye pain or swelling or impaired vision.
- Severe skin tissue damage: A potential symptom is blackening of the skin.

If you notice any signs of these side effects, stop using HEMLIBRA® and FEIBA® (aPCC) and talk to your doctor immediately.

HEMLIBRA has no or negligible influence on the ability to drive and operate machinery.

WHAT SHOULD I BEAR IN MIND BEFORE TRAVELLING?



Documents:

Before travelling, make sure that you have the necessary documents. Depending on where you are travelling, you may need a customs certificate and a certificate from your doctor to ensure that you can bring your medicines into a country or take them on an airplane. You can request and/or download the customs certificate from HEMCOACH.DE.



Dose:

Before travelling, think about how many HEMLIBRA® vials you will need. Do not forget to take an additional dose just in case and to take enough injection equipment.



Refrigeration:

HEMLIBRA® may only be stored outside the refrigerator for up to 7 days. You must therefore ensure that you can refrigerate the medicine at your destination.



Air travel:

Place your medicines in your carry-on bag to ensure that they are not lost with your suitcase or exposed to very cold temperatures. Remember that HEMLIBRA® must not be stored above 30 °C or unrefrigerated for more than 7 days in total. It is therefore recommended to keep HEMLIBRA® chilled even when out of the house if travel durations are too long or if you potentially have to store the medication unrefrigerated again later. Injection equipment, including needles and syringes, may also be carried in your carry-on bag with a doctor's certificate.

WHAT DO I HAVE TO CONSIDER BEFORE MEDICAL PROCEDURES AND SURGERY?

Talk with your doctor about what needs to be done before any medical procedures or surgery. Your doctor can tell you what to consider and whether and when you should take any additional medicines.



HEMLIBRA® INJECTION INSTRUCTIONS

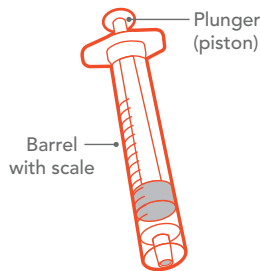
HEMLIBRA® INJEKTIONSANLEITUNG



REQUIRED INJECTION EQUIPMENT

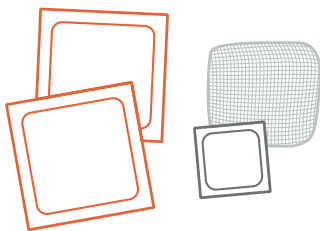


HEMLIBRA® vial(s) and instructions for use



Syringe

Use a disposable 1 mL syringe for injections of up to 1 mL. If the dose prescribed to you is more than 1 mL, you will need a disposable 2 mL syringe.

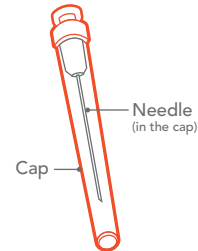


Alcohol swabs, gauze, plasters (not included in the injection kit)

Use a new alcohol swab for each vial.

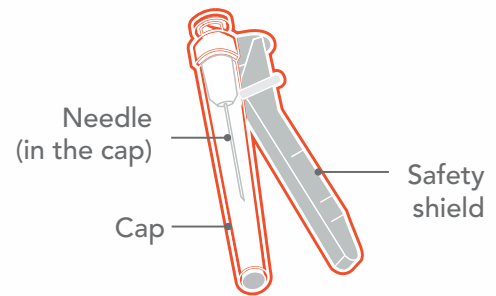
INJECTION KIT FOR USE WITH HEMLIBRA®

The injection kit contains the necessary tools for the injection of HEMLIBRA®. Your doctor or pharmacist can order the injection kit for you free of charge from Roche and Chugai.



Transfer needle with filter

The transfer needle is used to draw the medicine from the vial into the syringe.



Injection needle

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



Sharps disposal container

INJECTION KIT FOR USE WITH HEMLIBRA®

The injection equipment (alcohol swabs, gauze, plasters) can be ordered free of charge from HEMCOACH.DE.



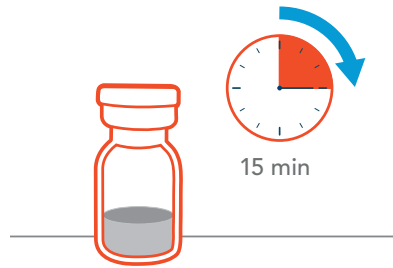
FOR USE WITH HEMLIBRA®

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

Before using HEMLIBRA® yourself for the first time, your doctor or other healthcare professional will show you the necessary preparations, the correct dosage and the appropriate injection technique.

Talk to your doctor or the healthcare professional if you have any questions

ARE YOU READY?



Start preparing for the injection:

15 minutes before the injection.

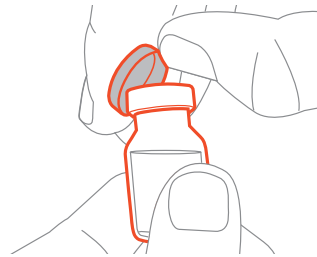
Take the vial(s) you need out of the refrigerator and verify that the outer carton and the labels say HEMLIBRA®.

Check the concentration and the expiry date of all vials and set them on a clean surface out of direct sunlight for 15 minutes. Set out the injection equipment.



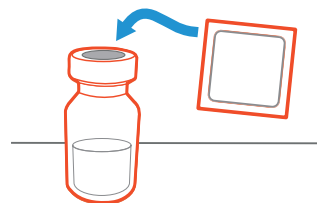
1

Wash your hands thoroughly with soap and water.



2

Remove the vial cap(s) and dispose of them in your sharps disposal container.



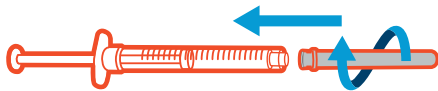
3

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



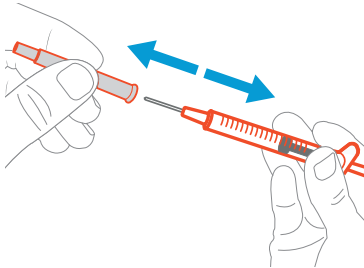
IMPORTANT INFORMATION

- Use each vial only once: After the injection, throw away any unused HEMLIBRA® solution left in the vial together with the vial. Do not keep any leftover medicine for later use.
- Only use syringes and injection needles prescribed to you by your doctor.
- Syringes, transfer needles and injection needles are for single use only.
- Do not use the injection needle to draw HEMLIBRA® from the vial.
- Dispose of all used syringes and needles properly.
- For further information on the storage and use of HEMLIBRA®, please refer to "My HEMLIBRA® treatment – the most important questions and answers" and on WWW.HEMCOACH.DE.



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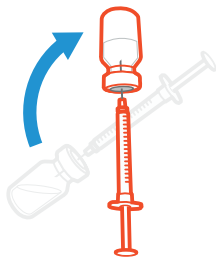
Remove the packaging from the transfer needle with filter. Place the transfer needle onto the syringe, push and twist clockwise until it is fully attached.



6

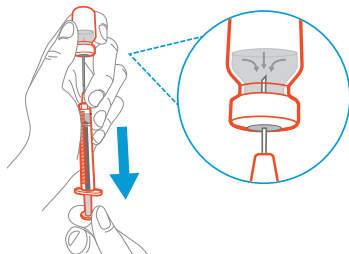
With the transfer needle pointing upwards, hold the body of the syringe firmly. Carefully remove the cap in one smooth movement, angled away from your body. Do not dispose of the cap. Place the transfer needle cap on a clean surface.

Do not touch the needle tip or place it on a surface after removing the cap.



8

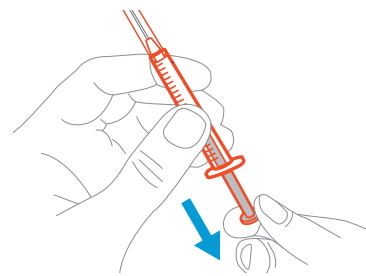
Keep the needle in the vial and turn the vial upside down.



10

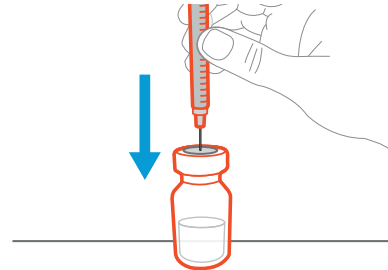
Press down on the syringe until the needle is located in the medicine. Then slowly pull back up on the plunger and fill the syringe with more medication than required.

Make sure that you do not pull the plunger out of the syringe.



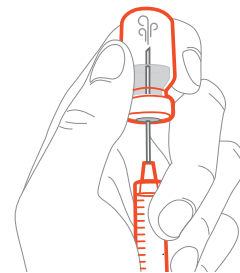
5

Slowly draw on the plunger and fill precisely the amount of air into the syringe that corresponds to the prescribed dose.



7

Hold the vial firmly and insert the transfer needle with filter into the vial. To do so, hold the body of the syringe firmly and insert it straight into the middle of the stopper from above.



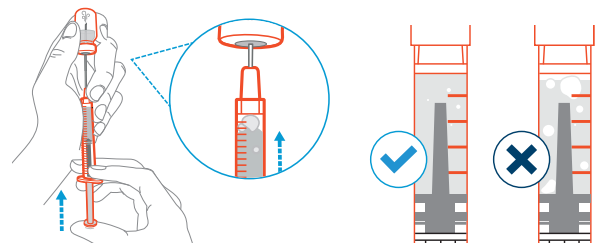
9

Press down on the syringe plunger to spray out the air from the syringe into the space above the medicine.

Do not press any air into the medicine itself, as this could lead to air bubbles or foaming.

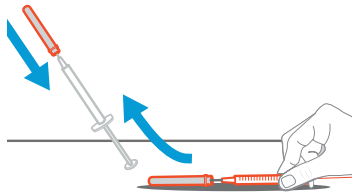
Keep the plunger pressed down with your finger.

Do not press any air into the medicine itself, as this could lead to air bubbles or foaming.



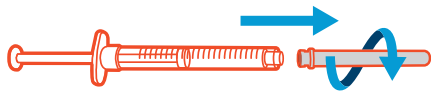
11

Keep the needle in the vial and check the syringe for larger air bubbles. Large air bubbles can result in too small a dose being administered. Remove larger air bubbles by tapping the syringe barrel with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to remove large air bubbles from the syringe. If the syringe contains the medication in the dose precisely prescribed or less, slowly pull the plunger until there is more medicine in the syringe than you require for your prescribed dose. Again, make sure that you do not pull the plunger out of the syringe entirely. Repeat the steps above until you have removed all larger air bubbles. Do not use the transfer needle to inject the medication, as this can cause pain and bleeding.



12

Remove the syringe and the transfer needle from the vial. Slide the transfer needle into the cap and slide the cap over the needle in an ascending movement so that it is fully covered. Once the needle is covered, press down on the cap to attach it fully.

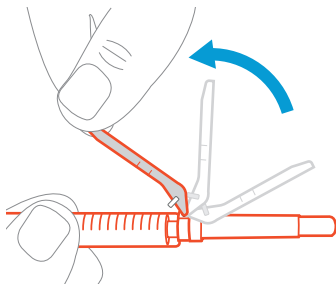


14

Remove the transfer needle from the syringe by twisting anti-clockwise and pulling carefully.

Dispose of the used transfer needle in a sharps disposal container.

Use the filled syringe immediately.



16

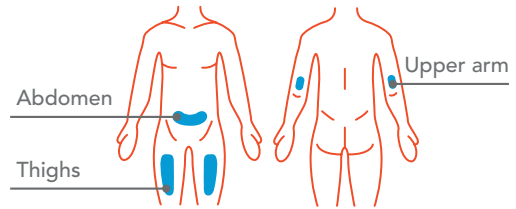
Move the safety shield away from the needle toward the syringe barrel.

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USE OF MULTIPLE VIALS

If your prescribed dose is greater than the amount of medicine in the vial, draw up the entire solution for injection.

Then simply scroll to the **"Combining vials"** section and continue as described there.



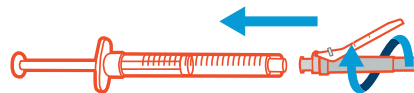
13

Clean the selected injection site with an alcohol swab. Then let the skin dry for 10 seconds and do not touch it again before the injection.

You can inject at the following regions of the body:

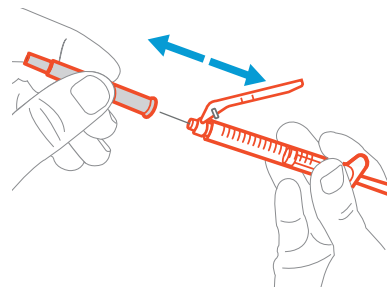
- Thighs (front and middle)
- Abdomen, except 5 cm around the navel
- Outer area of the upper arm (only if a caregiver administers the injection).

Change injection sites for each injection. The distance to the previous injection site should be at least 2.5 cm. Do not inject areas that could be irritated by clothing. Do not inject into skin that is red, injured, sensitive or hard or into moles, scars or bruises.



15

Place the injection needle on the syringe, press and turn it clockwise until it snaps fully into place.

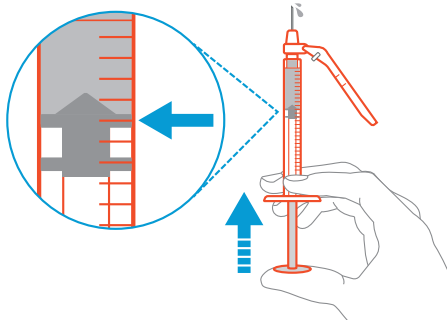


17

The cannula tip is aimed upwards if the safety cover is pointing upwards.

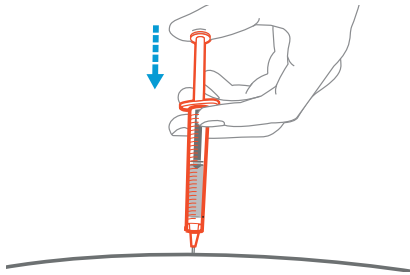
Pull the cap of the injection needle off the syringe and dispose of it in the sharps disposal container. Do not touch the needle tip and make sure that the syringe does not come into contact with surfaces.

If the needle is bent or damaged, do not try to straighten it or to use the medicine.



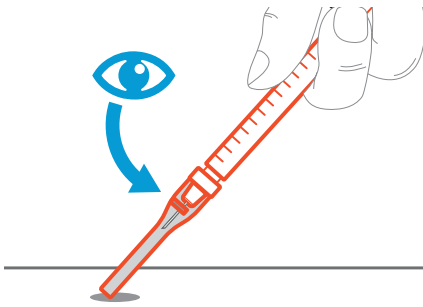
18

Hold the syringe with the needle pointing upwards and push the plunger in the syringe slowly to the correct dose. The top rim of the plunger must be exactly in line with the mark on the syringe for your prescribed dose.



20

Hold the syringe in that position and let go of the skin fold. Push the plunger down carefully and slowly inject all of the medicine. Remove the needle and the syringe from the injection site at the same angle you inserted it.



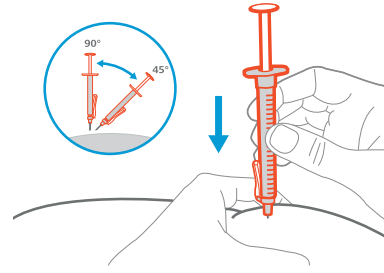
22

If you do not hear a "click", check whether the needle is fully covered by the safety shield. Make sure that your fingers always stay behind the safety shield.



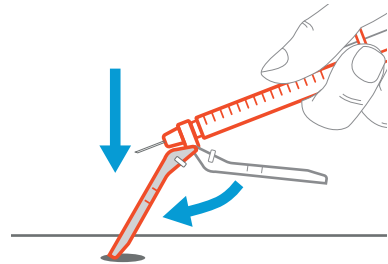
24

Record the injection of the medicine in your treatment diary.



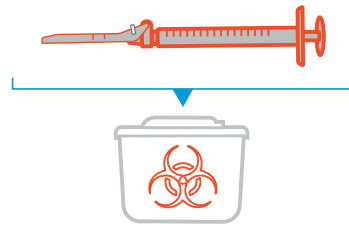
19

Pinch the skin at the chosen injection site to create a fold and insert the needle fully into it at an angle of 45 to 90 degrees. While inserting the needle, do not hold or push on the plunger.



21

Flip the safety shield 90 degrees away from the syringe barrel and press the safety shield down against a flat surface or with your finger until you hear a "click".



23

Do not remove the used injection needle from the syringe and do not recap the injection needle. Discard used needles and syringes directly in a sharps disposal container.

!

AFTER INJECTION

Do not rub the injection site after injection. If blood drops form at the injection site, press a sterile cotton pad on the injection site until the bleeding stops. If a bruise develops, gently press an ice pack onto the site. If the bleeding does not stop, talk to your doctor.

COMBINING VIALS

If you need more than one vial to get to your prescribed dose, follow these steps after drawing up the medicine from the first vial:

- Remove the syringe with the attached filter transfer needle from the vial.
- Using one hand, slide the filter transfer needle into the cap and slide the cap over the syringe in an ascending movement.
- Once the needle is covered, push the cap of the filter transfer needle onto the syringe until it is fully attached.
- Remove the filter transfer needle from the syringe by twisting anti-clockwise and pulling carefully.
- Dispose of the used filter transfer needle in a sharps disposal container.
- Place a new filter transfer needle onto the syringe. Push and twist clockwise until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.
- Insert the needle into the second vial and draw up the required amount of medicine as described.
- After having drawn up the correct dose of HEMLIBRA®, continue with step 12.



IMPORTANT INFORMATION

You must use a transfer needle with a filter each time you draw medicine from a new vial.

Different concentrations of HEMLIBRA® (e.g. 30 mg/mL and 150 mg/mL) can be combined, but not injected in a single syringe. Make sure that you don't use more than 2 millilitres (mL) per injection.



For more information about HEMLIBRA®, please refer to WWW.HEMCOACH.DE. In the login area, you can also watch an instruction video about how to inject HEMLIBRA®.



MORE INFORMATION

Do you have questions, problems or are you unsure about your HEMLIBRA® treatment?
Feel free to talk to your doctor about your concerns.

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