HEMLIBRA®

Emicizumab (30mg/ml, 150mg/ml)

What is in this leaflet

What HEMLIBRA is used for

HEMLIBRA is a medicine used for treating patients of all ages with haemophilia A (congenital factor VIII deficiency):

- who have developed factor VIII inhibitors
- who have not developed factor VIII inhibitors with:
  - severe disease (the factor VIII blood level is less than 1%)
  - moderate disease (the factor VIII blood level is from 1% to 5%) with severe bleeding phenotype.

Haemophilia A is an inherited condition caused by a lack of factor VIII, an essential substance required for blood to clot and stop any bleeding.

The medicine prevents bleeding or reduces bleeding episodes in people with this condition.

Some patients with haemophilia A can develop factor VIII inhibitors (antibodies against factor VIII) which stop the replacement factor VIII from working.

How HEMLIBRA works

HEMLIBRA restores the function of missing activated factor VIII that is needed for effective clotting. Its structure is different from factor VIII, therefore HEMLIBRA is not affected by factor VIII inhibitors.

Before you use HEMLIBRA

- *When you must not use it*

Do not take HEMLIBRA:

- if you are allergic to emicizumab or any of the other ingredients of this medicine (listed in Product Description). If you are not sure, talk to your doctor, pharmacist or nurse before using HEMLIBRA.

- *Before you start to use it*

Warnings and precautions

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

Talk to a 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.

Children below the age of 1 year

In children less than one year of age, the blood system is still developing. If your child is less than one year old, your doctor may prescribe HEMLIBRA only after carefully weighing the expected benefits and risks of using this product.

Using a bypassing agent while receiving HEMLIBRA

- Before you start using HEMLIBRA, talk to your doctor and carefully follow their instructions on when to use a bypassing agent and the dose and schedule you should use. HEMLIBRA increases the ability of the blood to clot. Therefore, the dose of bypassing agent required may be lower than the dose you used before starting HEMLIBRA.
- Use aPCC only if no other treatment can be used. If aPCC is required, talk to your doctor in case you feel you need a total of more than 50 units/kg of aPCC. For more information on using aPCC while receiving HEMLIBRA, see in Side Effects.
- Despite limited experience with concomitant administration of anti-fibrinolytics with aPCC or rFVIIa in patients treated with HEMLIBRA, you should know that there may be a possibility of thrombotic events using anti-fibrinolytics administered intravenously in combination with aPCC or rFVIIa.

Laboratory tests

Tell your doctor if you are using HEMLIBRA before you have laboratory tests to measure how well your blood is clotting. This is because HEMLIBRA in the blood may interfere with some laboratory tests, leading to inaccurate results.

Pregnancy and lactation

- You should use an effective method of birth control (contraception) during treatment with HEMLIBRA and for 6 months after your last injection of HEMLIBRA.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Your doctor will consider the benefit of you taking HEMLIBRA against the risk to your baby.

A patient card and guide (for patients and caregivers), which contains important safety information that you need to be aware of, may be obtained from your doctor. Keep this patient card with you at all times and show it to any healthcare provider, pharmacist or laboratory professional you see.

- *Taking other medicines*

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

HEMLIBRA may interfere with some medicines which include:

- aPCC
- recombinant FVIIa (rFVIIa)

How to use HEMLIBRA

HEMLIBRA is provided in single-use vials as ready to use solution which does not need to be diluted. A doctor qualified to care for patients with haemophilia will start you on treatment with HEMLIBRA. Always use this medicine exactly as your

doctor has told you. Check with your healthcare provider if you are not sure.

Keeping a record
Each time you use HEMLIBRA, record the name and batch number of the medicine.

- *How much to use*

The dose of HEMLIBRA depends on your weight and your doctor will calculate the amount (in mg) and corresponding amount of HEMLIBRA solution (in mL) to be injected:

- Loading dose regimen: Weeks 1 to 4: The dose is 3 mg for every 1 kg you weigh, injected once a week.
- Maintenance dose regimen: Week 5 and onwards: The dose is either 1.5 mg for every 1 kg you weigh, injected once a week, 3 mg for every 1 kg you weight, injected every 2 weeks, or 6 mg for every 1 kg you weigh, injected every 4 weeks.

The decision, to use either the 1.5 mg/kg once weekly, 3 mg/kg every two weeks, or 6 mg/kg every four weeks maintenance dose, should be made in consultation with your doctor and, where applicable, with your caregiver.

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

The amount of HEMLIBRA solution given in each injection must not be more than 2 mL.

Where to inject HEMLIBRA

- Your doctor will show you and/or your caregiver which areas of the body are suitable for injecting HEMLIBRA.
- The recommended places to give an injection are: the front of the waist (lower abdomen), upper outer arms, or the front of the thighs. Use only recommended places for injection.
- For each injection, use a different area of the body to the one you used last time.
- Do not give injections where the skin is red, bruised, tender, hard, or areas where there are moles or scars.
- When using HEMLIBRA, any other medicines injected under the skin should be given in a different area.

Using syringes and needles

- A syringe, a transfer needle with or without filter or a vial adapter with or without filter, and an injection needle are used to draw up the HEMLIBRA solution from the vial into the syringe and to inject it under the skin.
- Syringes, transfer needles with or without filter or vial adapter with or without filter, and injection needles are not provided in this pack.
- Make sure that you use a new injection needle for each injection and dispose of it after a single use.
- A 1 mL syringe should be used for an injection up to 1 mL of HEMLIBRA solution.
- A 2 to 3 mL syringe should be used for an injection greater than 1 mL and up to 2 mL of HEMLIBRA solution.

- *When to use it*

If you inject HEMLIBRA yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the Instructions for Use (available in package insert).

- HEMLIBRA is given by injection under the skin (subcutaneously).
- Your doctor or nurse will show you and/or your caregiver how to inject HEMLIBRA.
- Once you and/or your caregiver have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.
- To correctly insert the needle under the skin, pinch a fold of loose skin at the clean injection site with your free hand. Pinching the skin is important to ensure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injecting into a muscle could cause discomfort.
- Prepare and give the injection under clean and germ-free conditions using “aseptic technique”. Your doctor or nurse will give more information about this.

- *How long to use it*

Use this medicine for the duration that your doctor recommends. Do not stop using HEMLIBRA without talking to your doctor. If you stop using HEMLIBRA, you may no longer be protected against bleeding.

If you have any further questions on the use this medicine, ask your doctor, pharmacist or nurse.

- *If you forget to use it*

- If you forget your scheduled injection, inject the forgotten dose as soon as possible before the day of the next scheduled dose. Then, continue to inject the medicine 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, pharmacist or nurse.

- *If you use too much (overdose)*

If you use more HEMLIBRA than you are supposed to, tell your doctor immediately. This is because you may be at risk of developing side effects such as blood clots. Always use HEMLIBRA exactly as your doctor has told you, and check with your doctor, pharmacist or nurse if you are not sure.

While you are using HEMLIBRA

- *Things you must do*

Use this medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists who are treating you that you are using HEMLIBRA.

- *Things you must not do*

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give HEMLIBRA to anyone else, even if they have the same condition as you.

- *Things to be careful of*

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This medicine is not likely to affect your ability to drive or use machine.

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

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

- Destruction of red blood cells (thrombotic microangiopathy):
- Confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, vague belly (abdominal) or back pain, feeling sick (nausea), being sick (vomiting) or urinating less – these symptoms may be signs of thrombotic microangiopathy.
- Blood clots (thromboembolism):
- Swelling, warmth, pain or redness – these symptoms may be signs of a blood clot in a vein near the surface of the skin.
- Headache, numbness in your face, eye pain or swelling or problems with your vision – these symptoms may be signs of a blood clot in a vein behind your eye.
- Blackening of the skin – this symptom may be a sign of severe damage to the skin tissue.

Other side effects when using HEMLIBRA
Very common (may affect more than 1 in 10 people):

- a reaction in the area the injection was given (redness, itching, pain)
- headache
- joint pain

Common (may affect up to 1 in 10 people):

- fever
- muscle aches
- diarrhea
- itchy rash or hives (urticaria)
- skin rash

Uncommon (may affect up to 1 in 100 people):

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of HEMLIBRA

- *Storage*

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial label after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original pack in order to protect from light.

Once removed from the refrigerator, unopened vials may be kept at room temperature (below 30°C) for up to 7 days. After storage at room temperature, unopened vials may be returned back to the refrigerator. The total time the medicine is stored at room temperature should not be more than 7 days.

Discard vials that have been kept at room temperature for more than 7 days or exposed to temperatures above 30°C.

Once transferred from the vial to the syringe, use HEMLIBRA straight away. Do not refrigerate the solution in the syringe.

Before using the medicine, check the solution for particles or discoloration. The solution should be colourless to slightly yellow. Do not use this medicine if it is cloudy, discoloured, or contains visible particles.

- *Disposal*

Medicines should not be disposed of via wastewater or household wate. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

HEMLIBRA is a solution for injection under the skin (subcutaneous) and is for single-use only.

HEMLIBRA is a colourless to slightly yellow liquid.

Each pack of HEMLIBRA contains 1 glass vial.

- *Ingredients*

Active ingredient:
emicizumab

Each vial of HEMLIBRA contains:

- 30 mg (1 mL at a concentration of 30 mg/mL),
- 60 mg (0.4 mL at a concentration of 150 mg/mL),
- 105 mg (0.7 mL at a concentration of 150 mg/mL),
- 150 mg (1 mL at a concentration of 150 mg/mL)

of emicizumab.

Inactive ingredients:

- L-Arginine
- L-Histidine
- L-Aspartic acid
- LPoloxamer 188
- Water for Injection

What is needed for HEMLIBRA administration and is not contained in this pack
A syringe, a transfer needle with or without filter or a vial adapter with or without filter, and an injection needle are needed to withdraw the

HEMLIBRA solution from the vial to a syringe and inject it under the skin.

- *MAL numbers:*

HEMLIBRA 30mg/ml Solution for Injection (MAL19056106ARZ)
HEMLIBRA 150mg/ml Solution for Injection (MAL19056107ARZ)

Manufacturer
Made for F. Hoffmann-La Roche Ltd
Basel, Switzerland by

- Chugai Pharma Manufacturing Co., Ltd, Utsunomiya City, Japan
- Samsung Biologics Co., Ltd., Incheon 21987, Republic of Korea

Product Registration Holder
Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya,
Selangor, Malaysia.

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