Hemlibra®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Hemlibra?

Hemlibra contains the active ingredient emicizumab. Hemlibra is used for routine prophylaxis in children, adolescents and adults with haemophilia A. For more information, see Section 1. Why am I using Hemlibra? in the full CMI.

2. What should I know before I use Hemlibra?

Do not use if you have ever had an allergic reaction to Hemlibra, any other proteins that are of hamster origin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or**

are pregnant or plan to become pregnant or are breastfeeding.

If you have haemophilia A with inhibitors, it is very important you talk to your doctor about using bypassing agents before using Hemlibra. For more information, see Section 2. What should I know before I use Hemlibra? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hemlibra and affect how it works. Tell your haemophilia doctor or nurse if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Hemlibra?

- The dose of Hemlibra is dependent on your weight and frequency of injection. Your haemophilia doctor or nurse will tell you how much to inject.
- Hemlibra is given by injection under the skin (subcutaneously). Once you have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.

More instructions can be found in Section 4. How do I use Hemlibra? in the full CMI.

5. What should I know while using Hemlibra?

Things you should do	• Tell any doctor, dentist, pharmacist or nurse you visit that you are using Hemlibra. • If you are receiving Hemlibra and FEIBA-NF (Factor VIII inhibitor bypassing fraction), call your doctor immediately if you or your caregiver notices any symptoms of thrombotic microangiopathy (TMA) or blood clots and stop using Hemlibra and FEIBA-NF. • Call your doctor immediately if you or your caregiver feel Hemlibra is no longer helping your condition (e.g. if you notice an increase in bleeds). • Call your doctor immediately if you become pregnant while using Hemlibra.

Things you should not do	• Do not stop using Hemlibra or change the dosage without checking with your doctor.
Looking after your medicine	• Store in a refrigerator between 2°C to 8°C. Protect from light. Do not shake the vial. Do not freeze it. • Keep the vial in the box until it is time to use it. Do not use Hemlibra if it has been out of the refrigerator for more than 7 days or if the expiry date has passed. Do not refrigerate the solution in the syringe.

For more information, see Section 5. What should I know while using Hemlibra in the full CMI.

6. Are there any side effects?

Common side effects can include injection site reaction, joint pain or muscle aches, diarrhoea, skin rash or hives and fever. Serious side effects can include angioedema; and when Hemlibra is used with FEIBA-NF there has been thrombotic microangiopathy, blood clots in small blood vessels (in a vein near the surface of the skin or behind the eye) and also severe damage to the skin tissue/blackening. For more information, including what

to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Hemlibra increases the potential for your blood to clot. Stop prophylactic use of bypassing agents the day before starting Hemlibra prophylaxis. Carefully follow your doctor's instructions regarding when to use an on-demand bypassing agent, and the dose and schedule you should use. Hemlibra may cause serious side effects when used with aPCC (FEIBA-NF®) (see Section 6. Are there any side effects?).

Hemlibra®

Active ingredient: *emicizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hemlibra. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hemlibra.**

Where to find information in this leaflet:

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1. Why am I using Hemlibra?

Hemlibra contains the active ingredient emicizumab. Hemlibra belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are a type of protein that recognises and binds to a target in the body.

Hemlibra is used for routine prophylaxis in children, adolescents and adults with haemophilia A. This means it prevents bleeding or reduces the number of bleeding episodes. Hemlibra can be used for routine prophylaxis whether or not you have inhibitors to factor VIII.

Hemlibra works like factor VIII, by binding to the same clotting factors, which helps your blood to clot. However, because emicizumab is different to factor VIII, it works whether or not inhibitors are present.

This medicine is used to prevent bleeding or reduce the number of bleeding episodes in people with haemophilia A (“routine prophylaxis”). It is not to be used "on-demand" to treat bleeds once they occur.

2. What should I know before I use Hemlibra?

Warnings

Do not use Hemlibra if:

- you are allergic to emicizumab, any of the ingredients listed at the end of this leaflet, or any other proteins that are of hamster origin.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

If you are on routine prophylaxis with another agent before changing to Hemlibra:

- you must stop prophylaxis with bypassing agents the day before starting Hemlibra.
- you may continue prophylaxis with factor VIII for the first 7 days of treatment with Hemlibra.

If you have haemophilia A with inhibitors, it is very important you talk to your doctor about when and how to use bypassing agents to treat bleeds while using Hemlibra. Examples of bypassing agents include FEIBA-NF® and NovoSeven® RT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Hemlibra and affect how it works:

FEIBA-NF, factor VIII inhibitor bypassing fraction (also known as activated prothrombin complex concentrate, aPCC):

- Be aware there are serious and potentially life-threatening side effects of using FEIBA-NF while receiving Hemlibra (see Section 6. Are there any side effects).
- Avoid using FEIBA-NF unless no other treatment options are available. However, if FEIBA-NF is

required, talk to your doctor about how much to use. Do not use more than 50 units/kg of FEIBA-NF except under medical supervision.

Any other blood product, including NovoSeven® recombinant coagulation factor VIIa (also known as activated factor VII or eptacog alfa) or any form of factor VIII:

- Talk to your doctor and carefully follow their instructions on using these medicines while receiving Hemlibra. You may need different amounts of these medicines or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hemlibra.

4. How do I use Hemlibra?

Treatment with Hemlibra should be started under the supervision of a specialist doctor experienced in the treatment of haemophilia A.

Each time you use Hemlibra, record the name and batch number of the medicine.

How much to use

- The dose of Hemlibra is dependent on your weight and frequency of injection.
- Weeks 1 to 4: the dose is 3 milligrams for every 1 kilogram you weigh, injected once a week.

- Week 5 and onwards: the dose will depend on whether you will continue to inject Hemlibra once a week or change to once every 2 weeks or once every 4 weeks.
- Continue using your medicine for as long as your doctor tells you.

How to inject Hemlibra

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.

Follow all instructions given to you by your haemophilia doctor or nurse carefully. They may differ from the information contained in this leaflet.

Read the Instructions for Use leaflet for detailed instructions on how to inject Hemlibra available at: https://www.medsinfo.com.au/media/roihemli (Transfer needle with filter) or https://www.medsinfo.com.au/media/roihemlv (Vial adapter with filter)

The Instructions for Use leaflet is also provided in each box of Hemlibra. If you do not understand the Instructions for Use, ask your haemophilia doctor or nurse for help.

- Hemlibra is given by injection under the skin (subcutaneously).
- **Do not inject Hemlibra into a vein or muscle.** 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 result in an uncomfortable injection.

- Your doctor or nurse will show you how to inject Hemlibra.
- Once you have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.
- An injection should not be attempted until proper training has been given by the doctor or nurse on the correct injection technique.
- If a child would like to self-inject the medicine, the child’s healthcare provider and the parent or caregiver should agree on whether it is appropriate for them to do so. Self-injection for children below the age of 7 years is not recommended.
- Check the solution for particles or discolouration before using the medicine. It should be colourless to slightly yellow. **Do not inject it** if the solution is cloudy, discoloured, or contains visible particles.
- Prepare and give the injection under clean and germ-free conditions using "aseptic technique".
- A syringe, a transfer needle with filter or a vial adapter with filter and an injection needle are needed to withdraw Hemlibra solution from the vial into the syringe and inject it under the skin. Syringes, transfer needles with filter or vial adapters with filter and injection needles are supplied separately to the medicine.
- **Make sure that you use a new injection needle for each injection and dispose of it after a single use.**

- Use a 1 mL syringe to inject up to 1 mL of Hemlibra solution. Use a 2-3 mL syringe to inject greater than 1 mL and up to 2 mL of Hemlibra solution.

If you forget to use Hemlibra

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 next dose on your usual scheduled dosing day.

Do not inject a double dose on the same day to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your haemophilia doctor or nurse.

If you have trouble remembering to use your medicine, ask your haemophilia doctor or nurse for some hints.

If you use too much Hemlibra

If you think that you have used too much Hemlibra, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. This is because you may be at risk of developing side effects such as blood clots. You may need urgent medical attention.

5. What should I know while using Hemlibra?

Things you should do

- Carefully follow your doctor's instructions about the use of bypassing agents when using Hemlibra if you have haemophilia A with inhibitors.
- Tell your doctor that you are using Hemlibra if you are about to have any coagulation blood tests.

Call your doctor straight away if:

- **you or your caregiver feel Hemlibra is no longer helping your condition** (e.g. if you notice an increase in bleeds). Your doctor will try to understand what is causing this. It is uncommon, but it might mean that you have developed antibodies to Hemlibra, which caused Hemlibra to stop working. If Hemlibra is no longer helping, a change to your haemophilia treatment may be required.
- **you or your caregiver notices any symptoms of thrombotic microangiopathy (TMA) or blood clots** (see Section 6. Are there any side effects) and stop using Hemlibra and FEIBA-NF.
- **you become pregnant while using Hemlibra**.

Keep all of your doctor's appointments so that your progress can be checked.

Always carry with you your Patient Card.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Hemlibra.

Things you should not do

- Do not use Hemlibra "on-demand" to treat bleeds once they occur.
- Do not use Hemlibra to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine or change the dosage without checking with your doctor.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Be careful before you drive or use any machines or tools until you know how Hemlibra affects you.

Looking after your medicine

- Keep the vial in the box until it is time to use it.
- Store in a refrigerator between 2°C to 8°C. Protect from light.
- Do not shake the vial and do not freeze it.

- If necessary, 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 length of time the medicine is stored at room temperature should not be more than 7 days.
- **Do not use Hemlibra if it has been out of the refrigerator for more than 7 days or if the expiry date has passed.**
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature before preparing an injection. Use Hemlibra straight away after transferring it from the vial to the syringe.
- **Do not refrigerate the solution in the syringe.**

Follow the instructions in the carton on how to take care of your medicine properly.

Dispose of used vials, needles, vial adapters, vial/needle caps and used syringes in a sharps/puncture-proof container.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your haemophilia doctor, pharmacist or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection-site reactions: • Skin redness • Itching • Pain in the injection area **Joint or muscle related:** • Joint pain • Muscle aches **Stomach related:** • Diarrhoea • Nausea or vomiting • Abdominal pain **Skin related:** • Rash • Hives (urticaria)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Flushing **Eye symptoms:** • Itchy, watery eyes **Other:** • Fever • Fatigue or lightheadedness	

Serious side effects

Serious side effects	What to do
These serious side effects are uncommon and have been reported in patients who are receiving Hemlibra after the use of FEIBA-NF. **Blood related:** • Blood clots in small blood vessels (thrombotic microangiopathy (TMA)): confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, abdominal or	**Stop using Hemlibra and FEIBA-NF and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your caregiver notice any of these serious side effects.**

Serious side effects	What to do
back pain, feeling sick (nausea), being sick (vomiting) or urinating less • Blood clot in a vein near the surface of the skin (thrombophlebitis superficial): swelling, warmth, pain or redness • Blood clot in a vein behind the eye (cavernous sinus thrombosis): headache, numbness around the face, eye pain or swelling vision impairment **Skin related:** • Severe damage/ blackening of the skin tissue (skin necrosis) • Swelling mainly of the face, lips, tongue, throat/or extremities which may cause difficulty in breathing and swallowing (angioedema) **Respiratory symptoms:**	

Serious side effects	What to do
• Difficulty breathing or shortness of breath • Wheezing or whistling sound while breathing • Coughing **Other:** • Loss of consciousness • Rapid or weak pulse • Low blood pressure	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Hemlibra contains

Active ingredient **(main ingredient)**	emicizumab
Other ingredients **(inactive ingredients)**	• arginine • histidine • poloxamer • aspartic acid • water for injections
Potential allergens	not applicable

Do not take this medicine if you are allergic to any of these ingredients.

What Hemlibra looks like

Hemlibra is a colourless to slightly yellow solution in single-use, clear glass vials containing emicizumab:

- 30 mg in 1 mL (AUST R 293761)
- 60 mg in 0.4 mL (AUST R 293760)
- 105 mg in 0.7 mL (AUST R 293758)
- 150 mg in 1 mL (AUST R 293759)

Each pack contains 1 vial.

Who distributes Hemlibra

Hemlibra is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950 or www.medinfo.roche.com.

Please check with your pharmacist for the latest Consumer Medicine Information.

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