▼ **This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.**

Hemlibra®

emicizumab

Consumer Medicine Information

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 'Side Effects').

What is in this leaflet

This leaflet answers some common questions about Hemlibra. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Hemlibra against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Hemlibra is used for

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 contains the active substance emicizumab. This 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.

Haemophilia A is a bleeding condition present at birth, which is caused by missing or faulty factor VIII. Factor VIII is a blood clotting protein and blood does not clot normally when factor VIII is missing or not working properly.

Inhibitors to factor VIII develop in some people with haemophilia A after repeated use of factor VIII to prevent or treat bleeding. Inhibitors stop replacement factor VIII from working.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
This medicine is available only with a doctor's prescription.

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

Before you use Hemlibra

When you must not use it

Do not use Hemlibra if you have an allergy to:

- emicizumab
- any of the ingredients listed at the end of this leaflet
- any other proteins that are of hamster origin.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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.

Hemlibra increases the ability of your blood to clot. Therefore, the dose of bypassing agent or factor VIII needed to treat bleeds may be lower than the dose you used prior to starting Hemlibra (see "Using other medicines"). Your doctor will advise you.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.
Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Hemlibra.

Using other medicines

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

Some medicines and Hemlibra may interfere with each other. These include:

- FEIBA-NF, factor VIII inhibitor bypassing fraction (also known as activated prothrombin complex concentrate, aPCC)
- Any other blood product, including:
  - NovoSeven®, recombinant coagulation factor VIIa (also known as activated factor VII or eptacog alfa)
  - Any form of factor VIII

These medicines may be affected by Hemlibra or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Be aware there are serious and potentially life-threatening side effects of using FEIBA-NF while receiving Hemlibra.

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.

Serious side effects were reported when FEIBA-NF was used in patients also receiving Hemlibra in a clinical trial (see 'Side Effects').

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Hemlibra

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

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

If you do not understand the instructions on the box, ask your haemophilia doctor or nurse for help.

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. Your haemophilia doctor or nurse will tell you how much to inject.

- 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.

How to inject

Hemlibra is given by injection under the skin (subcutaneously).

Your doctor or nurse will show you and/or your caregiver how to inject Hemlibra.

Also refer to the Instructions for Use provided in the box.
The Instructions for Use describe how to prepare and administer an injection of Hemlibra.

Do not attempt self-injection until you are sure of how to do it.
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.

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.

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

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.

Prepare and give the injection under clean and germ-free conditions using "aseptic technique".

A syringe, a transfer needle 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 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.

You will be given more information about this by your haemophilia doctor or nurse.

Where to inject

Your haemophilia doctor or nurse will show you and/or your caregiver which areas of the body should be injected with Hemlibra.

Only give an injection in the recommended places.
The recommended places to inject yourself are: the front of the waist (lower abdomen) or the front of the thighs. If you have a caregiver, they can also inject Hemlibra into your upper outer arms.

Each time you inject, use a different recommended injection site.

Do not give injections where the skin is red, bruised, tender, hard, or areas where there are moles or scars.

When using Hemlibra, other medicines injected under the skin should be given in a different area.

Following these recommendations will help reduce the risk of injection site reactions (see Side Effects).

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

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 a double dose on the same day to make up for a forgotten dose.
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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Hemlibra.

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.

While you are using Hemlibra

Things you must do

If you have haemophilia A with inhibitors, follow carefully your doctor's instructions about the use of bypassing agents when using Hemlibra.
These may differ from before you started using Hemlibra.

If you are using bypassing agents, be aware of the possible symptoms of thrombotic microangiopathy (TMA) and blood clots which have occurred after use of FEIBA-NF in people receiving Hemlibra.
Possible symptoms of TMA and blood clots are listed under 'Side Effects'.

If you are about to have any coagulation blood tests, tell your doctor that you are using this medicine.
The presence of Hemlibra in the blood may interfere with some coagulation tests, leading to inaccurate results. Your doctor may need to do different tests which are not affected by Hemlibra.

Talk to your doctor immediately if you or your caregiver feels 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.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Always carry with you your Patient Alert Card.
The card contains important information about your treatment. It will alert other healthcare professionals that you are being treated with Hemlibra and that special measures are needed with the use of bypassing agents and laboratory tests.

If you become pregnant while using this medicine, tell your doctor.

Keep all of your doctor's appointments so that your progress can be checked.
Your doctor will check to make sure the medicine is working and discuss any unwanted side effects.

Things you must not do

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 lower the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Hemlibra.
This medicine helps most people with haemophilia A, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your haemophilia doctor or nurse to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- redness, itching, pain in the area the injection was given
- headache
- fever
- joint pain
- muscle aches
- diarrhoea

The above list includes the more common side effects of Hemlibra.

Uncommonly, serious side effects have been reported when FEIBA-NF was used in patients with inhibitors also receiving Hemlibra:

- Thrombotic microangiopathy (TMA) - a serious and potentially life-threatening condition where the lining of the blood vessels is damaged resulting in clots in small blood vessels. In some cases, this can cause damage to the kidneys and/or other organs.
- Blood clots - blood clots may form. In rare cases, a blood clot can block a blood vessel and may be life-threatening.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, abdominal or back pain, feeling sick (nausea), being sick (vomiting) or

urinating less - may be signs of thrombotic microangiopathy (TMA)
- Swelling, warmth, pain or redness - 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 vision impairment - may be signs of a blood clot in a vein behind your eye.
- Blackening of the skin - may be a sign of severe damage to the skin tissue.

Stop using Hemlibra and FEIBA-NF and talk to a doctor immediately if you or your caregiver notices any of the side effects listed above.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Hemlibra

Storage

Keep the vial in the box until it is time to use it.
If you take the vial out of the box it may not keep well.

Keep Hemlibra in a refrigerator where the temperature is between 2°C to 8°C and it is not exposed to light.

Do not shake the vial and do not put it in the freezer.

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 your medicine 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.

Disposal

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.

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

Product description

What it looks like

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

- 30 mg in 1 mL
- 60 mg in 0.4 mL
- 105 mg in 0.7 mL
- 150 mg in 1 mL

Each pack contains 1 vial.

Ingredients

Hemlibra contains emicizumab as the active ingredient. It also contains:

- arginine
- histidine
- poloxamer
- aspartic acid
- water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

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

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

Australian Registration Numbers:

- 30 mg/1 mL: AUST R 293761
- 60 mg/0.4 mL: AUST R 293760
- 105 mg/0.7 mL: AUST R 293758
- 150 mg/1 mL: AUST R 293759

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