# RiaSTAP®

## 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.

### 1. Why am I using RiaSTAP®?

RiaSTAP® contains the active ingredient human fibrinogen. RiaSTAP® is used for the treatment of acute bleeding in people with an absence or low level of human fibrinogen.

For more information, see Section 1.Why am I using RiaSTAP®? in the full CMI.

### 2. What should I know before I use RiaSTAP®?

Do not use if you have ever had an allergic reaction to RiaSTAP® 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 or are on a sodium controlled diet**.

For more information, see Section 2. What should I know before I use RiaSTAP®? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with RiaSTAP® and affect how it works.

For more information, see in Section 3. What if I am taking other medicines? in the full CMI.

### 4. How do I use RiaSTAP®?

- Treatment should be started and initiated by a doctor experienced in the treatment of coagulation conditions.
- If it is not injected immediately it must be stored below 25°C and used within 6 hours of reconstitution. The reconstituted solution should not be stored in the refrigerator.

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

### 5. What should I know while using Riastap®?

| | |
|---|---|
| **Things you should do** | • Remind any doctor, dentist or pharmacist you visit that you are using RiaSTAP®.<br>• Notice any signs of a serious side effect – this may indicate that the administration of RiaSTAP® needs to be stopped immediately. |
| **Things you should not do** | • Do not give or share your medicine with anyone else, even if they have the same condition as you.<br>• Do not mix RiaSTAP® with other medicines or diluents either before or during administration. |
| **Driving or using machines** | • RiaSTAP® has no or negligible influence on the ability to drive and use machines. |
| **Looking after your medicine** | • Store RiaSTAP® at 2°C to 8°C (Refrigerate. Do not freeze). Keep the vial in the outer carton, in order to protect it from light.<br>• Do not use after the expiry date. |

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

### 6. Are there any side effects?

All medicines can have side effects. sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. The most common side effect is fever. The more serious side effects include rash, or reddening of the skin, itching, difficulty breathing, feeling faint, dizziness and shortness of breath.

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.

# RiaSTAP®

**Active ingredient(s):** ***Human Fibrinogen***

## Consumer Medicine Information (CMI)

This leaflet provides important information about using RiaSTAP®. **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 RiaSTAP®.**

**Where to find information in this leaflet:**


1. Why am I using RiaSTAP®?
2. What should I know before I use RiaSTAP®?
3. What if I am taking other medicines?
4. How do I use RiaSTAP®?
5. What should I know while using RiaSTAP®?
6. Are there any side effects?
7. Product details


## 1. Why am I using RiaSTAP®?

**RiaSTAP® contains the active ingredient human fibrinogen.** RiaSTAP® is made from human plasma (this is the liquid part of the blood).

**RiaSTAP® for intravenous (into the vein) injection is used for the treatment of acute bleeding in people with an absence or low level of human fibrinogen (congenital lack of fibrinogen).**

Human fibrinogen is a protein which is important for blood clotting (coagulation). If you have missing or malfunctioning fibrinogen the blood does not clot as quickly as it should which results in an increased tendency of bleeding. The replacement of human fibrinogen with RiaSTAP® will help to temporarily correct the clotting in patients with fibrinogen deficiency.

## 2. What should I know before I use RiaSTAP®?

### Warnings

#### Do not use RiaSTAP® if:

- you are allergic to human fibrinogen, or any of the ingredients listed at the end of this leaflet.

#### Talk to your doctor before using RiaSTAP®:

There is an increased risk of blood clots (thrombosis), particularly

- in case of a high dose or repeated doing
- if you have had a heart attack (a history of coronary heart disease or myocardial infarction)
- if you have just had surgery
- if you suffer from liver disease
- if you will be having surgery soon
- in newborn infants
- if you are more likely to suffer from blood clots than normal.

Your doctor will consider carefully the benefit of treatment with RiaSTAP® compared with the risk of these complications.

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.

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

This medicine should only be used if clearly needed during pregnancy or breastfeeding.

### Virus safety

RiaSTAP® is made from human plasma (this is the liquid part of blood). When products are made from human blood or plasma and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or parvovirus B19. There could also be other infectious agents some of which may not yet have been discovered.

To reduce the risk of infection extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to kill and remove viruses. These special treatments are considered effective against certain viruses known as enveloped viruses (such as HIV and hepatitis B and C) and also for the non-enveloped virus hepatitis A.

The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Despite these measures, the risk of transmitting infection cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this medicine with your doctor.

### RiaSTAP® contains sodium

RiaSTAP® contains up to 164 mg sodium (approximately 7.1 mmol) per 1g fibrinogen (vial). Please take this into account if you are on a sodium controlled diet.

## 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 affect the way other medicines work.

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

## 4. How do I use RiaSTAP®?

### How much to use

The dose of RiaSTAP® you need and the duration of your treatment will depend on:

- the severity of the disease
- the site and intensity of the bleeding
- your clinical condition.

Your doctor will determine the dose suitable for you.

### When to use RiaSTAP®

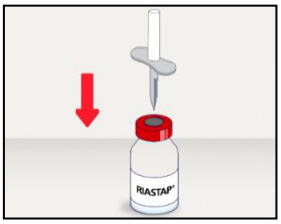
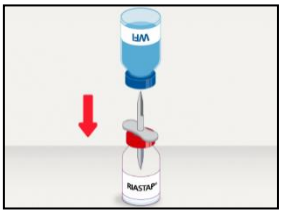
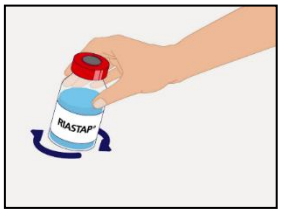
- Treatment should be started and initiated by a doctor experienced in the treatment of coagulation conditions.
- Your doctor will discuss with you when you should be given RiaSTAP®.

### Preparing RiaSTAP® for administration

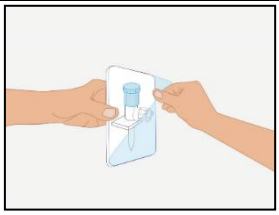
The following steps are used as a guide only. Please contact your doctor if you have any questions.

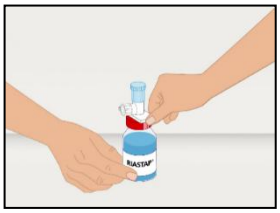
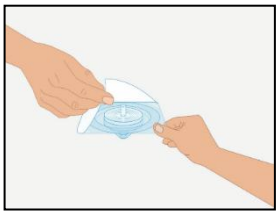
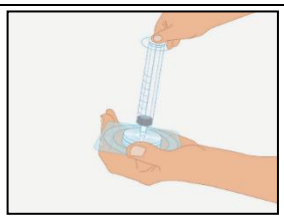
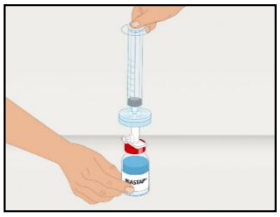
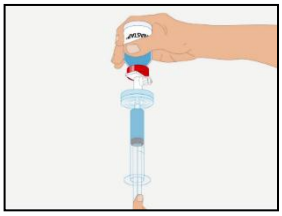
| | |
|---|---|
| 1. Ensure you have all the required components:<br>• one vial of 1 g RiaSTAP®<br>• one vial of 50 mL Water for Injections (WFI)<br>• one transfer set<br>• one dispensing pin<br>• one syringe filter. | |
| 2. Allow the vials of RiaSTAP® and WFI to reach room temperature prior to use, which may take up to one hour. Do not warm the WFI in hot water. | |
| 3. Remove jewellery, watches, rings, etc. | |
| 4. Wash hands with soap and water, dry with a clean towel. | |
| 5. Select an appropriate work area with good lighting and a surface which can be cleaned. | |
| 6. Using a clean cloth or paper towel, clean the preparation area with methylated spirits. | |

**Instructions for RiaSTAP® reconstitution**

| | |
|---|---|
| 7. Remove the cap from the RiaSTAP® vial to expose the central portion of the rubber stopper. |  |
| 8. Clean the surface of the rubber stopper with an antiseptic solution and allow to dry. |  |
| 9. Remove the safety cap from one end of the provided transfer set and pierce the stopper of the RiaSTAP® vial. |  |
| 10. Remove the safety cap from the other end of the transfer set, invert the WFI vial, apply gentle pressure to pierce the stopper and transfer the contents into the RiaSTAP® vial. |  |
| 11. Discard the WFI vial and remove the transfer set from the RiaSTAP® vial.<br>Gently swirl the RiaSTAP® vial to ensure the product is fully dissolved.<br>Avoid strong shaking which causes formation of foam. The powder should be completely reconstituted within max. 15 minutes (generally within 5 to 10 minutes). |  |

**Instructions for administration preparation**

| | |
|---|---|
| 12. Open the plastic blister containing the dispensing pin. |  |

| | |
|---|---|
| 13. Take the provided dispensing pin and insert into the stopper of the vial with the reconstituted RiaSTAP®.<br>After the dispensing pin is inserted, remove the cap. After the cap is removed, do not touch the exposed surface. |  |
| 14. Open the blister with the provided syringe filter. |  |
| 15. Screw the syringe (not supplied) onto the filter. |  |
| 16. Screw the syringe with the mounted filter onto the dispensing pin. |  |
| 17. Draw the reconstituted RiaSTAP® into the syringe.<br>18. When completed, remove the syringe filter, dispensing pin and empty vial from the syringe, dispose of appropriately, and proceed with administration. |  |

After reconstitution the solution should be clear or slightly opalescent, that is it might sparkle when held up to the light but must not contain any obvious particles.

Do not mix RiaSTAP® with other medicinal products or diluents either before or during administration.

**RiaSTAP® should be used for one person on one occasion only.**

RiaSTAP® should be administered by slow intravenous injection / infusion and should not exceed 5 mL per minute.

**If it is not injected immediately it must be stored below 25°C and used within 6 hours of reconstitution. The reconstituted solution should not be stored in the refrigerator.**

Any unused portion remaining in the vial must be discarded appropriately.

Every time that RiaSTAP® is injected, the date of administration, batch number and injected volume should be recorded.

### If you forget to use RiaSTAP®

RiaSTAP® should only be used as instructed by your doctor. The dosage and duration will depend on the severity of your condition.

**Consult your doctor is you have missed a dose to avoid overdose risks (blood clots).**

### If you use too much RiaSTAP®

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

Overdose may enhance the risk of blood clots (thrombosis).

Your doctor should regularly check your blood clot status during your treatment.

**If you have any questions consult your doctor.**

## 5. What should I know while using RiaSTAP®?

### Things you should do

**Call your doctor straight away if you:**

Notice signs or symptoms of a serious side effect. This may be a sign of a serious allergy or anaphylactic reaction. The administration of RiaSTAP® should be stopped immediately.

Remind any doctor, dentist or pharmacist you visit that you are using RiaSTAP®.

### Things you should not do

- Do not stop using this medicine suddenly unless instructed by your doctor.
- Do not give or share your medicine with anyone else, even if they have the same condition as you.
- Do not mix RiaSTAP® with other medicines or diluent either before or during administration.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how RiaSTAP® affects you.**

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

### Looking after your medicine

- Store at 2°C to 8°C (Refrigerate. Do not freeze).
- Keep the vial in the carton in order to protect it from light.
- Do not use after the expiry date.

- RiaSTAP® does not contain a preservative so the made-up solution should preferably be used immediately.

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

**Keep it out of the sight and reach of children.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 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 doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects | What to do |
|---|---|
| • fever. | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

### Serious side effects

| Serious side effects | What to do |
|---|---|
| • feeling faint (fall in blood pressure)<br>• reddening of the skin<br>• rash (over the body)<br>• difficulty in breathing<br>• dizziness<br>• itching<br>• shortness of breath.<br><br>Some of these side effects may indicate that a blood clot (thrombosis) has formed. | **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** |

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

**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

RiaSTAP® is usually given in a hospital and is only available with a doctor's prescription.

### What RiaSTAP® contains

| | |
|---|---|
| **Active ingredient (main ingredient)** | Human fibrinogen |
| **Other ingredients (inactive ingredients)** | Albumin<br>Arginine hydrochloride<br>Sodium chloride<br>Sodium citrate |

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

### What RiaSTAP® looks like

RiaSTAP® is a white powder and is supplied with water for injections as solvent.

RiaSTAP® comes in a pack which also contains:

- one vial of diluent (50 mL Water for Injections)
- one transfer set
- one dispensing pin
- one syringe filter.

1 g: AUST R 162828

### Who distributes RiaSTAP®

RiaSTAP® is supplied in Australia by

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189-209 Camp Road

Broadmeadows VIC 3047

Australia

**For Medical / Technical Enquiries**
TOLL FREE: 1800 642 865

**For Customer Service Enquiries**
TOLL FREE: 1800 063 892

customerservice@cslbehring.com.au

www.cslbehring.com.au

This leaflet was prepared in March 2025.

® Registered trademark of CSL Limited Group of Companies