

# ELOCTATE®

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## 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.

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### 1. Why am I using ELOCTATE?

ELOCTATE contains the active ingredient efmoroctocog alfa. Efmoroctocog alfa is a factor VIII protein necessary for forming clots in the blood and helps to control or prevent bleeding. ELOCTATE is used for the management of haemophilia A (congenital factor VIII deficiency).

For more information, see Section [1. Why am I using ELOCTATE?](#) in the full CMI.

### 2. What should I know before I use ELOCTATE?

Do not use if you have ever had an allergic reaction to ELOCTATE, efmoroctocog alfa or other factor VIII replacement factors, 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.**

For more information, see Section [2. What should I know before I use ELOCTATE?](#) in the full CMI.

### **3. What if I am taking or using other medicines?**

Tell your doctor or Haemophilia Treatment Centre if you are taking or using any other medicines including any that you get without a prescription from your pharmacy, supermarket, or health food shop. For more information see Section [3. What if I am taking or using other medicines?](#) in the full CMI.

### **4. How do I use ELOCTATE?**

- Your doctor will decide what dose you will receive. Do not use more than the recommended dose.
- ELOCTATE is administered by slow injection directly into your vein.
- ELOCTATE comes in a vial of sterile powder to cake and a pre-filled syringe containing solvent. These need to be mixed before use.

**More instructions and how to use ELOCTATE can be found in Section [4. How do I use ELOCTATE?](#) in the full CMI.**

## 5. What should I know while using ELOCTATE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor immediately if bleeding is not controlled after using ELOCTATE.</li><li>• Tell your doctor immediately if you become pregnant.</li><li>• Tell any other doctors, dentist, or pharmacist you visit that you are using ELOCTATE.</li><li>• Keep all your appointments with your doctor and any blood tests.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or change the dose without checking with your doctor.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in the refrigerator at 2°C to 8°C. Do not freeze.</li><li>• Store in a cool, dry place away from moisture, heat, or sunlight.</li></ul>

- Keep ELOCTATE in the pack until it is time to use it.

For more information, see Section [5. What should I know while using ELOCTATE?](#) in the full CMI.

## **6. Are there any side effects?**

Less serious side effects include joint pain or swelling, muscle aches, tenderness or weakness, general feeling of discomfort, feeling hot or cold, headache, stomach pain, high or low blood pressure, dizziness, cough, light headedness, back pain, slow heartbeat, chest pain, rash and loss of taste. A serious side effect is an allergic reaction with symptoms of shortness of breath, wheezing or difficulty breathing, chest pain or discomfort, swelling of the face, lips tongue or other parts of the body rash or hives. 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.

# ELOCTATE®

**Active ingredient:** *efmoroctocog* alfa (recombinant coagulation factor VIII Fc fusion protein)

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## Consumer Medicine Information (CMI)

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

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

- [1. Why am I using ELOCTATE?](#)
- [2. What should I know before I use ELOCTATE?](#)
- [3. What if I am taking or using other medicines?](#)
- [4. How do I use ELOCTATE?](#)
- [5. What should I know while using ELOCTATE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ELOCTATE?

**ELOCTATE contains the active ingredient efmoroctocog alfa.** People with haemophilia A lack sufficient factor VIII to control bleeding. ELOCTATE works by replacing factor VIII to enable blood to clot.

**ELOCTATE is used to:**

- **control and prevent bleeding episodes,**
- **routinely prevent and reduce the frequency of bleeding episodes,**
- **reduce bleeding before, during, and after surgery.**

ELOCTATE does not contain von Willebrand factor. Therefore, it is not suitable for use in Von Willebrand's disease.

## **2. What should I know before I use ELOCTATE?**

### **Warnings**

**Do not use ELOCTATE if:**

- you have an allergy to ELOCTATE or other factor VIII replacement factors, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- take any medicines for any other condition

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. There is no information on the use of ELOCTATE during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

Talk to your doctor if you are breastfeeding or plan to breastfeed. It is not known whether ELOCTATE passes into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding.

### **3. What if I am taking or using other medicines?**

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

Your doctor or Haemophilia Treatment Centre have more information on medicines to be careful with or avoid while using this medicine.

## 4. How do I use ELOCTATE?

### How much to use

- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- Your doctor will decide what dose you will receive. This will depend on your individual need for replacement factor VIII therapy.
- Your doctor may change the dose during your treatment.
- Do not stop using ELOCTATE or change the dosage, without checking with your doctor unless you have an allergic reaction.

### How to use it

ELOCTATE is administered by slow injection into your veins.

ELOCTATE is provided as a powder in a vial and a pre-filled syringe containing a sterile solvent also known as a diluent. These need to be mixed before use.

- Mix the ELOCTATE powder with the diluent provided only when you are ready to use it. **Do not shake ELOCTATE when mixing it.** Shaking can damage this medicine.
- If you mix the powder and solvent and are interrupted, you can keep the mixed product for a maximum of 6

hours if you store it below 30°C and protect it from direct sunlight. **Do not put it in the freezer.**

- Always inspect ELOCTATE after it has been mixed and before use. It should be clear to slightly rainbow-like (opalescent) and colourless. **Do not inject if the solution is discoloured or cloudy, or contains particles.**
- Refer to the leaflet in the pack for step-by-step instructions on how to prepare and inject ELOCTATE.
- ELOCTATE is for single use in one patient only. Dispose of any unused solution, vials, and needles in a sharps bin. See additional information under, Getting rid of any unwanted medicine.

If you have any questions about how to use ELOCTATE, talk to your doctor, or Haemophilia Treatment Centre, or telephone 1800 818 806 (In Australia) or 0800 283 684 (In New Zealand).

## **If you forget to use ELOCTATE**

If you miss your dose at the usual time, use your dose as soon as you remember and resume your normal dosing schedule.

**Do not use a double dose to make up for the dose you missed.**

If you are not sure what to do, ask your doctor or Haemophilia Treatment Centre.

## **If you use too much ELOCTATE**

If you think that you or anyone else may have used too much ELOCTATE or have been given too much ELOCTATE, you may need urgent medical attention.

### **You should immediately:**

- contact your doctor, or
- go to the Emergency Department at your nearest hospital, or
- phone the Poisons Information Centre **(by calling 13 11 26 in Australia or 0800 764 766 in New Zealand).**

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using ELOCTATE?**

### **Things you should do**

**Tell your doctor immediately if:**

- **your bleeding is not controlled after using ELOCTATE.**
- **you become pregnant while on treatment with ELOCTATE.**

**Before you use or take any other medicine, talk to your doctor or Haemophilia Treatment Centre.**

**If you are about to have any blood tests, tell your doctor that you are using ELOCTATE.**

**Keep all your appointments with your doctor so your progress can be checked and have any blood tests your doctor requests.**

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

## **Things you should not do**

- Do not use more than the recommended dose.
- Do not give ELOCTATE to anyone else even if they have the same condition as you.
- Do not use ELOCTATE to treat any other complaints unless a doctor tells you to.
- Do not stop using ELOCTATE or change the dosage without checking with your doctor.

## **Driving or using machines**

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

## **Looking after your medicine**

- Keep ELOCTATE in the pack until it is time to use it, protected from light.
- Store in the refrigerator at 2°C to 8°C. Do not freeze ELOCTATE.
- If necessary, you can keep ELOCTATE out of the refrigerator for a single 6-month period. If out of the

refrigerator, store the sealed carton in a cool, dry place below 30°C. Record the date ELOCTATE was removed from the refrigerator on the carton. Do not use ELOCTATE that has been out of the refrigerator for more than 6 months.

- Once reconstituted, you can keep ELOCTATE at room temperature (below 30°C) for up to 6 hours. Protect the product from direct sunlight. Do not freeze.
- Do not use ELOCTATE after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or damaged, return it to your Haemophilia Treatment Centre or Australian Red Cross Blood Service for disposal.

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

**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 it is out of date, ask your Haemophilia Treatment Centre 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, ask your doctor, Haemophilia Treatment Centre, or pharmacist if you have any further questions about side effects.

## Less serious side effects in previously treated patients

Less serious side effects	What to do
<p><b>Joint or muscle-related</b></p> <ul style="list-style-type: none"> <li>• Joint pain</li> <li>• Joint swelling</li> <li>• Aching muscles, muscle tenderness or weakness not caused by exercise</li> <li>• Back pain</li> </ul> <p><b>Heart-related</b></p> <ul style="list-style-type: none"> <li>• High blood pressure</li> <li>• Low blood pressure including dizziness or lightheaded</li> <li>• Slow heartbeat</li> <li>• Chest pain</li> </ul> <p><b>Others</b></p> <ul style="list-style-type: none"> <li>• General feeling of discomfort</li> <li>• Headache</li> <li>• Rash</li> <li>• Feeling cold</li> <li>• Feeling hot</li> <li>• Dizziness</li> </ul>	<p><b>Speak to your doctor or Haemophilia Treatment Centre if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Taste disturbance or loss of taste</li> <li>• Cough</li> <li>• Stomach pain</li> </ul>	

### **Less serious side effects in previously untreated patients**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Rash</li> </ul>	<p><b>Speak to your doctor or Haemophilia Treatment Centre if you have any of these less serious side effects and they worry you.</b></p>

### **Serious side effects in both previously treated and previously untreated patients**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Factor VIII inhibition</b></p> <ul style="list-style-type: none"> <li>• easily bruising or bleeding due to factor VIII inhibition</li> </ul> <p><b>Allergy-related</b></p>	<p><b>Stop using ELOCTATE and call your doctor straight away or go straight to the Emergency Department at your nearest hospital</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Swelling of your face, lips, tongue, or other parts of your body, rash or hives,</li> <li>● Shortness of breath, wheezing, difficulty breathing, chest pain or discomfort.</li> </ul>	<p><b>if you notice any of these serious side effects.</b></p> <p><b>These side effects are rare in previously treated patients.</b></p>

ELOCTATE may increase the risk of abnormal blood clots forming in your body if you are at risk of developing blood clots.

Your body can make antibodies called “inhibitors” against ELOCTATE which may stop ELOCTATE from working properly.

**Tell your doctor, Haemophilia Treatment Centre, 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](http://www.tga.gov.au/reporting-problems) in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor, Haemophilia Treatment Centre or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

### **What ELOCTATE contains**

#### **Powder in a vial**

<b>Active ingredient (main ingredient)</b>	efmoroctocog alfa
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sucrose</li><li>• sodium chloride</li><li>• histidine</li><li>• calcium chloride dihydrate</li><li>• polysorbate 20</li></ul>
<b>Potential allergens</b>	Not applicable

#### **Solvent in a pre-filled syringe**

<b>Active ingredient (main ingredient)</b>	Not applicable
<b>Other ingredients</b>	<ul style="list-style-type: none"><li>• sodium chloride</li></ul>

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• water for injections</li> </ul>
<b>Potential allergens</b>	Not applicable

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

ELOCTATE contains 14 mg of sodium per vial.

## **What ELOCTATE looks like**

ELOCTATE consists of:

- 1 vial of sterile ELOCTATE white to off-white powder to cake
- 1 pre-filled syringe containing a clear and colourless solvent
- 1 sterile vial adapter for mixing the powder and solvent

ELOCTATE is available in the following strengths:

- 250 International Units (IU)
- 500 International Units (IU)
- 1000 International Units (IU)
- 2000 International Units (IU)
- 3000 International Units (IU)

## **Who distributes ELOCTATE**

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

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### **Australian Registration Numbers**

ELOCTATE 250 IU Aust R 210521

ELOCTATE 500IU Aust R 210519

ELOCTATE 1000 IU Aust R 210525

ELOCTATE 2000 IU Aust R 210524

ELOCTATE 3000 IU Aust R 210520

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