ELOCTATE® (E-lok-tate)
efmoroctocog alfa (recombinant coagulation factor VIII Fc fusion protein) 250, 500, 750, 1000, 1500, 2000, 3000 IU/vial

Consumer Medicine Information (CMI)

What is in this Leaflet

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

If you have any questions about using this medicine, ask your doctor.

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

What ELOCTATE is used for

ELOCTATE is used for the management of haemophilia A (congenital factor VIII deficiency). ELOCTATE is used for:
- control and prevention of bleeding episodes
- routine prophylaxis to prevent and reduce the frequency of bleeding episodes
- reduction of bleeding before, during, and after surgery

ELOCTATE does not contain von Willebrand factor and therefore is not suitable for use in von Willebrand’s disease.

People with haemophilia A lack sufficient factor VIII to control bleeding. ELOCTATE works by replacing factor VIII to enable blood to clot.

There is no information on the use of this medicine in those below 12 years of age.

Ask your doctor if you have any questions about why ELOCTATE has been prescribed for you.

ELOCTATE is available only with a doctor’s prescription. This has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Before you use ELOCTATE

When you must not use it

Do not use ELOCTATE if you have an allergy to:
- ELOCTATE
- any of the other ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include difficulty breathing, chest tightness, swelling of the face, rash, or hives on the skin. If any of these signs occur, stop using ELOCTATE and see your doctor immediately.

Do not use ELOCTATE after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. Do not use ELOCTATE if the medicine is cloudy, contains particles or is discoloured. It should be clear to slightly opalescent and colourless.

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

Before you start to use it

Tell your doctor if you are pregnant or trying to become pregnant. It is not known whether ELOCTATE can affect the development of your baby if you use it during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known whether ELOCTATE passes into the milk and if it can harm your baby. Your doctor can discuss with you the possible risks involved. If you have not told your doctor about any of the above, tell them before you start using ELOCTATE.

Taking other medicines

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

Ask your doctor if you have any questions about medicines to be careful with or avoid while using ELOCTATE.

How to use ELOCTATE

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

Dosage

Your doctor will decide how much ELOCTATE you use. This will depend on your individual need for replacement factor VIII therapy. Your doctor may change the dose you use during your treatment.

Do not stop using ELOCTATE or change the dosage, without checking with your doctor unless you have an allergic reaction.

Starting ELOCTATE

ELOCTATE is given by slow injection directly into your veins.

ELOCTATE is provided as a powder and diluent which need to be mixed together before use. It is important to not shake ELOCTATE when mixing it. Shaking can damage this medicine.

Mix the ELOCTATE powder with the diluent provided only when you are ready to use it. If you mix the Powder and diluent and are interrupted, you can keep the mixed product for a maximum of 6 hours when stored at room
temperature (below 30°C). Do not put it in the freezer.

Always inspect ELOCTATE before use and after it has been mixed. The medicine should be clear to slightly 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 about how to prepare and inject ELOCTATE.

Single use vial: for use in one patient on one occasion only. Dispose of all unused solution, empty vials and used needles and syringes in a sharps bin.

Talk to your doctor, or telephone 1800 852 289 in Australia or 0800 852 289 in NZ, if you have any questions about how to use ELOCTATE.

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.

If you forget to use it
Use your dose of ELOCTATE as soon as you remember and then resume your normal dosing schedule.

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

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

If you use too much (overdose)
Immediately telephone the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), if you think you or anyone else may have used too much ELOCTATE.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using ELOCTATE

Things you must do
Tell your doctor immediately if bleeding is not controlled after using ELOCTATE.

If you become pregnant while on treatment with ELOCTATE, immediately tell your doctor.

Always talk to your doctor before taking any other medicine while you are using ELOCTATE.

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

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

Keep all your doctor’s appointments so that your progress can be checked. Your doctor may do blood tests before you start treatment and from time to time to monitor your progress.

Things you must not do
Do not use more than the recommended dose.

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

Do not stop using ELOCTATE or change the dosage, without checking with your doctor unless you have an allergic reaction.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:
- difficulty breathing, chest tightness, swelling of the face, rash, or hives

ELOCTATE may increase the risk of formation of abnormal blood clots in your body if you have risk factors for developing blood clots.

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

Tell your doctor if you notice anything that is making you feel unwell.

Side effects
Tell your doctor as soon as possible if you do not feel well while using ELOCTATE.

All medicines have side effects. Often they are not serious, but sometimes they can be. You may need medical attention if you get some side effects.

These are possible side effects and you may not experience any of them. Other side effects not listed below may occur in some people.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:
- joint pain or joint swelling
- general discomfort (malaise)
- feeling cold
- feeling hot
- headache
- stomach pain
- dizziness
- cough
- rash
- aching muscles, muscle tenderness or weakness, not caused by exercise
- taste disturbance or loss of taste (dysgeusia)
- high blood pressure
- low blood pressure (symptoms include dizziness or feeling lightheaded)
- slow heart beat (bradycardia)
- chest pain

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:
- difficulty breathing, chest tightness, swelling of the face, rash, or hives

ELOCTATE may increase the risk of formation of abnormal blood clots in your body if you have risk factors for developing blood clots.

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Tell your doctor if you notice anything that is making you feel unwell.

After using ELOCTATE

Storage
Keep your ELOCTATE in the carton until it is time to use it. The medicine should be protected from the light.

Keep ELOCTATE in the refrigerator at 2°C to 8°C.

Once reconstituted, you can keep ELOCTATE at room temperature (below 30°C) for up to 6 hours.

Do not store ELOCTATE or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Heat and dampness can destroy some medicines.

Do not freeze ELOCTATE. Do not place in the freezer or freezing compartment of a refrigerator.

Keep ELOCTATE where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

Product description

What it looks like
ELOCTATE comes as a white to off-white powder to cake in a glass vial. Each pack contains:
- 1 vial of sterile ELOCTATE powder
- 1 pre-filled syringe of diluent
- 1 sterile vial adapter reconstitution device

Ingredients
ELOCTATE is available in 7 vial sizes: 250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU and 3000 IU. Each vial contains the active ingredient efmoroctocog alfa as a sterile white to off-white powder to cake. When reconstituted with the provided diluent, it also contains:
- sucrose
- sodium chloride
- histidine
- calcium chloride
- polysorbate 20

Australian Register Numbers:
ELOCTATE 250 IU - AUST R 210521
ELOCTATE 500 IU - AUST R 210519
ELOCTATE 750 IU - AUST R 210523
ELOCTATE 1000 IU - AUST R 210525
ELOCTATE 1500 IU - AUST R 210522
ELOCTATE 2000 IU - AUST R 210524
ELOCTATE 3000 IU - AUST R 210520

Further information
You can get more information from your doctor, or by telephoning 1800 852 289 in Australia.

Supplier
ELOCTATE is supplied in Australia by:
Biogen Idec Australia Pty Ltd
ABN 30 095 760 115
Suite 1, Level 5
123 Epping Road
North Ryde NSW 2113
Australia

ELOCTATE is supplied in New Zealand by:
Biogen Idec NZ Limited
Auckland, New Zealand.

This leaflet was prepared in April 2015.

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