

ELOCTATE®

Efmoroctocog alfa (recombinant coagulation factor VIII Fc fusion protein) 250, 500, 750, 1000, 1500, 2000, 3000 IU/vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ELOCTATE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your doctor or your Haemophilia Treatment Centre to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from <http://www.bioverativ.com.au/therapies/haemophilia-b.aspx>.

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

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

Keep this leaflet with the medicine.

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 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 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.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Do not give this medicine to anyone else.

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 or other factor VIII replacement factors
- any of the ingredients listed at the end of this leaflet.

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.

If any of these signs occur, stop using ELOCTATE and see your doctor immediately.

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 Haemophilia Treatment Centre or Australian Red Cross Blood Service for disposal.

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 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.

Tell 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.

Tell your doctor if you are breast-feeding or planning 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.

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 or Haemophilia Treatment Centre if you are taking any other medicines, including any that you get 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.

How to use ELOCTATE

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 doctor or Haemophilia Treatment Centre for help.

How much to use

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.

How to use it

ELOCTATE is given by slow injection directly into your veins.

ELOCTATE is provided as a powder and sterile water for injections (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). Protect the product from direct sunlight.

Do not put it in the freezer.

Always inspect ELOCTATE after it has been mixed and before use.

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.

Use in one patient on one occasion only. Dispose of all unused solution, empty vials, and used needles and syringes into a sharps bin.

Talk to your doctor or Haemophilia Treatment Centre, or telephone 1800 207 753 in Australia or 0800 447 785 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 resume your normal dosing schedule.

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

This may increase the chance of you getting an unwanted side effect.

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

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26, in New Zealand telephone 0800 764 766) for advice, or go to Emergency at the nearest hospital, if you think that 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 or Haemophilia Treatment Centre before using any other medicine while you are using ELOCTATE.

Do not use more than the recommended dose.

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

Your doctor may do some blood tests before you start your treatment and from time to time during your treatment to monitor your progress.

Things you must not do

Do not use ELOCTATE to treat any other complaints unless your doctor tells you to.

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

Do not stop using your medicine or change the dosage without checking with your doctor.

Side effects

Tell your doctor or Haemophilia Treatment Centre as soon as possible if you do not feel well while you are using ELOCTATE.

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 doctor or Haemophilia Treatment Centre to answer any questions you may have.

Tell your doctor or Haemophilia Treatment Centre 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
- back pain
- low blood pressure (symptoms include dizziness or feeling lightheaded)
- slow heart beat (bradycardia)
- chest pain.

The above list includes the more common side effects of your medicine. If any of these persist or worsen, talk to your doctor.

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

- swelling of your face, lips, tongue or other parts of the body, rash or hives
- shortness of breath, wheezing, difficulty breathing, chest pain or discomfort.

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

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 or Haemophilia Treatment Centre if you notice anything that is making you feel unwell.

After using ELOCTATE

Storage

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

This medicine should be protected from light.

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

Do not freeze ELOCTATE.

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

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 where the temperature stays below 30°C. The

date that the product is removed from the refrigerator should be recorded on the carton.

Do not use any ELOCTATE that has been out of the refrigerator for more than 6 months (refer to Disposal below).

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 store ELOCTATE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry date has passed, ask your Haemophilia Treatment Centre 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.

ELOCTATE is available in 7 strengths: 250 IU, 500 IU, 750IU, 1000 IU, 1500IU, 2000 IU and 3000IU.

Ingredients

ELOCTATE contains efmoctocog alfa as the active ingredient.

Other ingredients:

- sucrose
- sodium chloride
- histidine
- calcium chloride
- polysorbate 20.

Further information

You can obtain more information from your doctor or your Haemophilia Treatment Centre, or by telephoning 1800 207 753 in Australia or 0800 447 785 in New Zealand.

Sponsor

ELOCTATE is supplied in Australia by:

Bioverativ Australia Pty Ltd
Suite 10,
79-83 High Street,
Kew
Victoria 3101

ELOCTATE is supplied in New Zealand by:

Bioverativ NZ Limited
Wellington, NZ

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ELOCTATE 250 IU - AUST R
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ELOCTATE 500 IU - AUST R
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ELOCTATE 750 IU - AUST R
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ELOCTATE 1000 IU - AUST R
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ELOCTATE 1500 IU - AUST R
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ELOCTATE 2000 IU - AUST R
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ELOCTATE 3000 IU - AUST R
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