

ALPROLIX®

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 ALPROLIX?

ALPROLIX contains the active ingredient eftrenonacog alfa (recombinant coagulation factor IX fusion protein). ALPROLIX is used for the management of haemophilia B (congenital factor IX deficiency). For more information, see Section [1. Why am I using ALPROLIX?](#) in the full CMI.

2. What should I know before I use ALPROLIX?

Do not use if you have ever had an allergic reaction to ALPROLIX or other factor IX 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, use 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 ALPROLIX?](#) in the full CMI.

3. What if I am taking 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 other medicines?](#) in the full CMI.

4. How do I use ALPROLIX?

- Your doctor will decide how much ALPROLIX you use. This will depend on your individual need for replacement factor IX therapy. Your doctor may change the dose you use during your treatment.
- ALPROLIX is given by slow injection directly into your veins.
- ALPROLIX comes in a vial of sterile powder to cake and a pre-filled syringe containing solvent, also known as diluent. These need to be mixed before use. More instructions can be found in Section [4. How do I use ALPROLIX?](#) in the full CMI.

5. What should I know while using ALPROLIX?

Things you should do

- Tell your doctor immediately if bleeding is not controlled after using ALPROLIX.

	<ul style="list-style-type: none"> ● If you become pregnant while on treatment with ALPROLIX, immediately tell your doctor. ● Tell any other doctors, dentist, or pharmacist you visit that you are using ALPROLIX. ● Keep all your appointments with your doctor and any blood tests.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● 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.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep your ALPROLIX in the pack until it is time to use it. ● This medicine should be protected from light. ● Keep ALPROLIX in the refrigerator at 2°C to 8°C.

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

6. Are there any side effects?

Some common side effects are headache, tingling or numbness in your mouth (paraesthesia), breath odour, fatigue, dizziness, taste disturbance or loss of taste (dysgeusia), pain or redness at site of infusion, easily bruising or bleeding due to factor IX inhibition, low blood pressure (symptoms include dizziness or feeling lightheaded), fast or irregular heartbeats, also called palpitations, pain in your side with blood in your urine (obstructive uropathy).

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.

ALPROLIX®

Active ingredient(s): Eftrenonacog alfa

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALPROLIX. **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 ALPROLIX.**

Where to find information in this leaflet:

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

1. Why am I using ALPROLIX?

ALPROLIX contains the active ingredient eftrenonacog alfa (recombinant coagulation factor IX fusion protein). ALPROLIX is used for the management of haemophilia B (congenital factor IX deficiency).

People with haemophilia B lack sufficient factor IX to control bleeding. ALPROLIX works by replacing factor IX to enable blood to clot.

ALPROLIX is used to

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

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

This medicine helps to control your condition but does not cure it.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ALPROLIX?

Warnings

Do not use ALPROLIX if:

- you are allergic to eftrenonacog alfa or other factor IX 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:

- have any other medical conditions

- 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 ALPROLIX during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

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

3. What if I am taking other medicines?

Tell your doctor or Haemophilia Treatment Centre 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.

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 ALPROLIX?

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 how much ALPROLIX you use. This will depend on your individual need for replacement factor IX therapy.
- Your doctor may change the dose you use during your treatment.
- Do not stop using ALPROLIX or change the dosage, without checking with your doctor unless you have an allergic reaction.

How to use ALPROLIX

- ALPROLIX is given by slow injection directly into your veins.
- ALPROLIX is for single use in one patient only.
- Dispose of all unused solution, empty vials, and used needles and syringes into a sharps bin.

Preparing ALPROLIX

- Refer to the leaflet in the pack for step-by-step instructions about how to prepare and inject ALPROLIX.

- ALPROLIX is provided as a powder and sterile sodium chloride solution 0.325% (diluent) which need to be mixed together before use.
- It is important to not shake ALPROLIX when mixing it.
- Shaking can damage this medicine.
- Mix the ALPROLIX 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 ALPROLIX before use and after it has been mixed.

Inspecting ALPROLIX

- The medicine should be clear to slightly opalescent and colourless.
- Do not inject if the solution is discoloured or cloudy or contains particles.

How long to use ALPROLIX

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

If you have any questions about how to use ALPROLIX, 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 ALPROLIX

Use your dose of ALPROLIX as soon as you remember and resume your normal dosing schedule.

Do not take a double dose to make up for the dose 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 ALPROLIX

If you think that you have used too much ALPROLIX, 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 for advice
 - by calling 13 11 26 if you are in Australia or
 - by calling 0800 764 766 if you are in New Zealand

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

5. What should I know while using ALPROLIX?

Things you should do

- Always talk to your doctor or Haemophilia Treatment Centre before taking any other medicine while you are using ALPROLIX.
- 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 ALPROLIX.
- 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.

When to call your doctor straight away:

Tell your doctor immediately if:

- Your bleeding is not controlled after using ALPROLIX.
- You become pregnant while on treatment with ALPROLIX, immediately tell your doctor.

Things you should not do

- Do not use more than the recommended dose.
- Do not use ALPROLIX 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.

Driving or using machines

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

Looking after your medicine

- Keep your ALPROLIX in the pack until it is time to use it.
- This medicine should be protected from light.
- Keep ALPROLIX in the refrigerator at 2°C to 8°C. Do not freeze ALPROLIX.
- If necessary, you can keep ALPROLIX 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 ALPROLIX that has been out of the refrigerator for more than 6 months (refer to Disposal below).
- Once reconstituted, you can keep ALPROLIX at room temperature (below 30°C) for up to 6 hours. Protect the product from direct sunlight.

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
<ul style="list-style-type: none">● headache● tingling or numbness in your mouth (paraesthesia)● breath odour● fatigue● dizziness● taste disturbance or loss of taste (dysgeusia)	<p>Speak to your doctor or Haemophilia Treatment Centre if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● pain at site of infusion ● low blood pressure (symptoms include dizziness or feeling lightheaded) ● fast or irregular heartbeats, also called palpitations ● pain in your side with blood in your urine (obstructive uropathy). 	

Less serious side effects in previously untreated patients

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

Serious side effects in both previously treated and previously untreated patients

Serious side effects	What to do
<p>Factor IX inhibition</p> <ul style="list-style-type: none"> • easily bruising or bleeding due to factor IX inhibition <p>Allergy related</p> <ul style="list-style-type: none"> • 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. 	<p>Call your doctor or Haemophilia Treatment Centre straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

ALPROLIX 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 ALPROLIX, which may stop ALPROLIX 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 as follows:

For Australia: Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

For New Zealand: Medsafe online at <https://www.medsafe.govt.nz/safety/report-a-problem.asp>

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 ALPROLIX contains

Powder in a vial

Active ingredient (main ingredient)	eftrenonacog alfa
Other ingredients	● sucrose

(inactive ingredients)	<ul style="list-style-type: none"> • histidine • mannitol • polysorbate 20
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Solvent in a pre-filled syringe

Active ingredient (main ingredient)	Not applicable
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium chloride • water for injections

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

ALPROLIX contains 6.4 mg of sodium per vial.

What ALPROLIX looks like

ALPROLIX consists of:

- 1 vial of sterile ALPROLIX white to off-white powder to cake
 - 1 pre-filled syringe containing solvent also known as diluent
 - 1 sterile vial adapter for mixing powder and solvent
- ALPROLIX is available in 6 strengths: 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU and 4000IU.
- ALPROLIX 250 IU - AUST R 209227
 - ALPROLIX 500 IU - AUST R 209223
 - ALPROLIX 1000 IU - AUST R 209224

- ALPROLIX 2000 IU - AUST R 209225
- ALPROLIX 3000 IU - AUST R 209226
- ALPROLIX 4000 IU - AUST R 315497

Who distributes ALPROLIX

ALPROLIX is supplied in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

Email: medinfo.australia@sanofi.com

ALPROLIX is supplied in New Zealand by:

sanofi-aventis new zealand limited

56 Cawley Street

Ellerslie, Auckland

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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