

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using ALTUVIIIIO?

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

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

2. What should I know before I use ALTUVIIIIO?

Do not use if you have ever had an allergic reaction to ALTUVIIIIO, efanesoctocog 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 ALTUVIIIIO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALTUVIIIIO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ALTUVIIIIO?

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

More instructions can be found in Section [4. How do I use ALTUVIIIIO?](#) in the full CMI.

5. What should I know while using ALTUVIIIIO?

Things you should do	<ul style="list-style-type: none">• Tell your doctor immediately if bleeding is not controlled after using ALTUVIIIIO.• Tell your doctor immediately if you become pregnant.• Tell any other doctors, dentist, or pharmacist you visit that you are using ALTUVIIIIO.• Keep all your appointments with your doctor and any blood tests.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Store in the refrigerator at 2°C to 8°C. Do not freeze.• Keep ALTUVIIIIO in the pack until it is time to use it to protect from sunlight.

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

6. Are there any side effects?

Less serious side effects include pain in extremity, back pain, joint pain, fever, headache, vomiting, itchy skin, red or dry skin, rash and reactions at the injection site. A serious side effect is an allergic reaction with symptoms of swelling of the face, rash, generalised itching, hives, tightness of the chest, difficulty breathing, burning and stinging at the injection site, chills, flushing, headache, low blood pressure, general feeling of being unwell, nausea, restlessness and fast heartbeat, feeling dizzy and loss of consciousness.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ALTUVIIIIO®

Active ingredient(s): *efanesoctocog alfa*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ALTUVIIIIO?

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

ALTUVIIIIO is used to:

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

Warnings

Do not use ALTUVIIIIO if:

- you have an allergy to ALTUVIIIIO 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

There is no information on the use of ALTUVIIIIO 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 ALTUVIIIIO 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 other medicines?

Tell your doctor, Haemophilia Treatment Centre, 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.

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

4. How do I use ALTUVIIIIO?

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 (in International Units or "IU"). This will depend on your weight and whether it is used for prevention or treatment of bleeding.
- Your doctor may change the dose during your treatment.
- Do not stop using ALTUVIIIIO or change the dosage, without checking with your doctor unless you have an allergic reaction.

How to use it

ALTUVIIIIO is administered by slow injection into your veins.

ALTUVIIIIO 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 ALTUVIIIIO powder with the diluent provided only when you are ready to use it. **Do not shake ALTUVIIIIO 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 3 hours if you store it below 30°C and protect it from direct sunlight. **Do not put it in the freezer.**

- Always inspect ALTUVIIIIO 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 cloudy or contains visible particles.
- Refer to the leaflet in the pack for step-by-step instructions on how to prepare and inject ALTUVIIIIO.
- ALTUVIIIIO 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 ALTUVIIIIO, talk to your doctor, or Haemophilia Treatment Centre staff, or telephone 1800 818 806 (In Australia).

If you forget to use ALTUVIIIIO

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 staff.

If you use too much ALTUVIIIIO

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

You should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital, or
- contact the Poisons Information Centre (phone: 13 11 26).

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

5. What should I know while using ALTUVIIIIO?

Things you should do

Tell your doctor immediately if:

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

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

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

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 ALTUVIIIIO.

Things you should not do

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

Driving or using machines

ALTUVIIIIO has no or negligible influence on your ability to drive and use machines.

Looking after your medicine

- Keep ALTUVIIIIO 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 ALTUVIIIIO.
- If necessary, you can keep ALTUVIIIIO 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 ALTUVIIIIO was removed from the refrigerator on the carton. Do not use ALTUVIIIIO that has been out of the refrigerator for more than 6 months.
- Once reconstituted, you can keep ALTUVIIIIO at room temperature (below 30°C) for up to 3 hours. Protect the product from direct sunlight. Do not freeze.
- Do not use ALTUVIIIIO 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 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

Do not throw away any medicines via the wastewater or household waste. 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

Less serious side effects	What to do
General body: <ul style="list-style-type: none"> • Pain in extremity (arms, hands, legs or feet) • Back pain 	Speak to your doctor or nurse if you have any

Less serious side effects	What to do
<ul style="list-style-type: none"> Arthralgia (joint pain) Fever <p>Nerves</p> <ul style="list-style-type: none"> Headache <p>Digestive system:</p> <ul style="list-style-type: none"> Vomiting <p>Skin:</p> <ul style="list-style-type: none"> Eczema (itchy, red or dry skin) Rash Urticaria (itchy skin) <p>Reactions at the injection site (including bruising and inflammation)</p>	of these symptoms.

Serious side effects

Serious side effects	What to do
<p>Factor VIII inhibition:</p> <ul style="list-style-type: none"> Easily bruising or bleeding due to factor VIII inhibition <p>Allergy-related:</p> <ul style="list-style-type: none"> Swelling of the face Rash Generalised itching Hives Tightness of the chest Difficulty breathing Burning and stinging at the injection site Chills Flushing Headache Low blood pressure General feeling of being unwell Nausea Restlessness and fast heartbeat Feeling dizzy Loss of consciousness 	<p>Stop using ALTUVIIIIO and call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Your body can make antibodies called “inhibitors” against factor VIII which may stop ALTUVIIIIO from working properly. You will be monitored carefully for the development of these inhibitors.

Tell your doctor, Haemophilia Treatment Centre staff, 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, Haemophilia Treatment Centre staff or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What ALTUVIIIIO contains

Powder in a vial

Active ingredient (main ingredient)	efanesoctocog alfa
Other ingredients (inactive ingredients)	sucrose calcium chloride dihydrate histidine arginine hydrochloride polysorbate 80

Solvent in a pre-filled syringe

Active ingredient (main ingredient)	Not applicable
Other ingredients (inactive ingredients)	water for injections

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

What ALTUVIIIIO looks like

ALTUVIIIIO consists of:

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

ALTUVIIIIO is available in the following strengths:

- 250 International Units (IU) - AUST R 492507
- 500 International Units (IU) - AUST R 492510
- 1000 International Units (IU) - AUST R 492505
- 2000 International Units (IU) - AUST R 492506
- 3000 International Units (IU) - AUST R 492508
- 4000 International Units (IU) - AUST R 492509

Who distributes ALTUVIIIIO

ALTUVIIIIO is supplied in Australia by:

sanofi-aventis australia pty ltd
International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Toll Free No: 1800 818 806

Email: medinfo.australia@sanofi.com

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