

Thymoglobuline®

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 Thymoglobuline?

Thymoglobuline contains the active ingredient rabbit anti-human thymocyte immunoglobulin. Thymoglobuline is used to treat and prevent kidney transplant rejection and to treat aplastic anaemia.

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

2. What should I know before I use Thymoglobuline?

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

3. What if I am taking other medicines?

Some medicines may interfere with Thymoglobuline 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 Thymoglobuline?

- Thymoglobuline will be given by a drip directly into one of your veins (intravenous infusion) in hospital by a doctor or nurse.
- The infusion will last about 6 hours for the first dose and 4 hours for doses after that.

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

5. What should I know while using Thymoglobuline?

Things you must do	<ul style="list-style-type: none">• Keep follow-up appointments with your doctor or clinic.• Have any blood tests when your doctor says to. Your doctor may wish to test your body's response to Thymoglobuline to make sure that the medicine is working properly.
Driving or using machines	<ul style="list-style-type: none">• Thymoglobuline should not normally interfere with your ability to drive or operate machinery but make sure you know how Thymoglobuline affects you before you drive a car, operate machinery, or do anything that may be dangerous if you are dizzy, lightheaded, tired or drowsy.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor that you drink alcohol
Looking after your medicine	<ul style="list-style-type: none">• Thymoglobuline is stored in the pharmacy or on the hospital ward and kept in the refrigerator, between 2°C and 8°C.

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

6. Are there any side effects?

Common side effects: generally feeling unwell, headaches soreness, aching muscles, muscle tenderness or weakness (not caused by exercise), nausea and vomiting, fever or chills, diarrhoea, dizziness or light-headedness, flushing or redness of the skin, Infections.

Serious side effects: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, local reaction around the infusion site such as redness, itchiness, tenderness, pain, discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars.

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.

Thymoglobuline

Active ingredient(s): rabbit anti-human thymocyte immunoglobulin

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Thymoglobuline?

Thymoglobuline contains the active ingredient rabbit anti-human thymocyte immunoglobulin. Thymoglobuline is an immunosuppressant or an anti-rejection medicine. It helps to suppress your immune system so that it does not attack healthy cells or tissues by mistake.

Thymoglobuline is used to treat and prevent kidney transplant rejection, and to treat aplastic anaemia.

Thymoglobuline works by lowering certain cells within your body's immune system which are likely to attack your transplanted organ or your bone marrow cells.

2. What should I know before I use Thymoglobuline?

Warnings

Do not use Thymoglobuline if:

- you are allergic to rabbit anti-human thymocyte immunoglobulin, other rabbit proteins, or any of the ingredients listed at the end of this leaflet.
- you have an active or chronic infection.

Check with your doctor if you:

- have any other medical conditions such as blood/bleeding related problems not related to aplastic anaemia, lowered immunity due to diseases such as HIV/AIDS or cancer.
- have or have had damage to the smallest blood vessels known as thrombotic microangiopathy (TMA).
- 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. Thymoglobuline is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Thymoglobuline passes into breastmilk. Breastfeeding is not recommended whilst receiving Thymoglobuline treatment.

3. What if I am taking other medicines?

Tell your doctor 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.

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

This is because some medicines can affect the way Thymoglobuline works or Thymoglobuline can affect how other medicines work. These include medicines which suppress your body's immune system such as: cyclosporin, tacrolimus, mycophenolate mofetil, azathioprine, and corticosteroids.

Taking these medicines in combination with Thymoglobuline may increase the risk of over-suppressing your body's immune system. You may need different amounts of these medicines, or you may need to take different medicines. Your doctor will determine which medicines and calculate the doses most suitable for you.

You may receive some of the medicines in the list above as part of your ongoing treatment after your kidney transplant.

Talk to your doctor before getting vaccinations while you are receiving Thymoglobuline.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Thymoglobuline.

4. How do I use Thymoglobuline?

How much to take / use

- **For organ transplant:** the amount of Thymoglobuline you receive will depend upon the organ you have received, your weight and whether you are taking other immunosuppressant medicine. Your doctor will calculate the dose most suitable for you.
- **For aplastic anaemia:** the amount of Thymoglobuline you receive will depend upon your weight and other medications you may be taking for your condition(s). Your doctor will calculate the dose most suitable for you.

When to take / use Thymoglobuline

- Thymoglobuline will be given by a drip directly into one of your veins (intravenous infusion) in hospital by a doctor or nurse.
- The infusion will last about 6 hours for the first dose and 4 hours for doses after that.
- **For organ transplant:** 3 to 9 days after transplantation to prevent rejection, or 7 to 14 days after transplantation to treat rejection.
- **For aplastic anaemia:** daily infusion for 5 days to treat aplastic anaemia.
- Approximately an hour before receiving Thymoglobuline, you may be given some medications such as an antihistamine, a corticosteroid and anti-pyretic (anti-fever) medicine. This will help reduce your chance of developing certain adverse reactions to Thymoglobuline.

If you receive too much Thymoglobuline

As Thymoglobuline is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Thymoglobuline **you should immediately:**

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

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

5. What should I know while using Thymoglobuline?

Things you must do

- Keep follow-up appointments with your doctor or clinic.
- Have any blood tests when your doctor says to. Your doctor may wish to test your body's response to Thymoglobuline to make sure that the medicine is working properly.

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

Driving or using machines

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

Thymoglobuline should not normally interfere with your ability to drive or operate machinery but make sure you know how Thymoglobuline affects you before you drive a car, operate machinery, or do anything that may be dangerous if you are dizzy, lightheaded, tired or drowsy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Thymoglobuline is stored in the pharmacy or on the hospital ward and kept in the refrigerator, between 2°C and 8°C.

Thymoglobuline should not be frozen.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Sometimes the effects of Thymoglobuline may not occur until months after it is used. These delayed effects may include an increased risk of infections.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Generally feeling unwell• Headaches• Soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)• Bruising or bleeding• Fatigue or tiredness• Nausea and vomiting• Fever or chills• Diarrhoea• Dizziness or light-headedness• Flushing or redness of the skin• Infections• Anaemia (tiredness, headaches, dizziness, looking pale)• Increased bilirubin levels in blood (jaundice or yellowing of skin and eyes)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Shortness of breath, wheezing or difficulty breathing• Swelling of the face, lips, tongue or other parts of the body• Local reaction around the infusion site such as redness, itchiness, tenderness, pain, discomfort, warmth, burning or	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
stinging, swelling or the formation of hard lumps or scars	these serious side effects.

Tell your doctor 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 or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Thymoglobuline contains

Active ingredient (main ingredient)	Rabbit anti-human thymocyte immunoglobulin
Other ingredients (inactive ingredients)	Glycine Sodium chloride Mannitol

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

What Thymoglobuline looks like

Thymoglobuline is a creamy white freeze-dried powder supplied in a 10 ml glass vial (AUST R 139787).

Who distributes Thymoglobuline

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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