THYMOGLOBULINE®

Rabbit anti-human thymocyte immunoglobulin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Thymoglobuline.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Thymoglobuline is used for

Organ Transplantation
You have been given a new transplanted kidney from another person because your own was no longer healthy. Your body recognises that this new organ is different from your organs and will try to reject it by attacking it in the same way it would attack germs that enter your body. This could make you ill again. The name of your medicine is Thymoglobuline. It belongs to a group of medicines called immunosuppressants (anti-rejection medicines). These medicines suppress your immune system and can help prevent your body from rejecting the transplanted kidney.

Aplastic Anaemia
Thymoglobuline is also used to treat aplastic anaemia, which is a serious condition in which your bone marrow can no longer produce enough blood cells.

Your doctor may have prescribed Thymoglobuline for another purpose.

How it works

Organ Transplantation:
Thymoglobuline works by lowering certain cells within your body's immune system which are likely to attack your transplanted organ.

Aplastic Anaemia:
Thymoglobuline works by lowering certain cells within your body's immune system, thus giving your bone marrow a chance to produce blood cells.

Before you are given Thymoglobuline

When you must not be given it

Do not take Thymoglobuline if you have an allergy to:

- Thymoglobuline
- rabbit proteins
- any of the ingredients listed at the end of this leaflet.

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
- skin rash, itching, hives or redness of the skin.

Tell your doctor if you have or have had any medical conditions, especially the following:

- blood or bleeding problems not related to aplastic anaemia
- lowered immunity due to diseases such as HIV / AIDS or cancer
- active lung infections
- high temperature (fever)
- active skin allergies, including rash and eczema
- other active skin problems, including recurring boils
- prolonged diarrhoea or vomiting
- tuberculosis (TB).

If you have not already told your doctor about any of the above, tell them before you take Thymoglobuline.

Do not have Thymoglobuline if you are pregnant or intend to become pregnant.
Thymoglobuline is not recommended for use during pregnancy.

Tell your doctor if you are breast-feeding.
It is not known whether Thymoglobuline passes into breast milk. Breastfeeding is not recommended whilst receiving Thymoglobuline treatment.

Do not have Thymoglobuline after the expiry date printed on the pack.

Do not have Thymoglobuline if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have Thymoglobuline, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have reacted to previous infusions with any of the following:

- life-threatening allergic reaction
- difficulty breathing
- swelling of the throat
- fainting or collapse
- shock-like state or being unresponsive for a long period of time
- fits or convulsions
- high temperature (greater than 40°C)
- severe skin reaction at the infusion site, including severe bruising.

Taking other medicines

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

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 (immunosuppressants), such as: cyclosporin, tacrolimus, mycophenolate mofetil, azathioprine, 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 (see section Additional Medications below).

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

How Thymoglobuline is given

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.

How much is given

Organ Transplant:
The amount of Thymoglobuline you receive will depend upon the organ which you have received, your weight and whether you are taking other immunosuppressant medicines. Your doctor will calculate the dose which is most suitable for you.

Aplastic Anaemia:
The amount of Thymoglobuline you receive will depend upon your weight and other medication which you may be taking for your condition. Your doctor will calculate the dose which is most suitable for you.

When it is given

Organ Transplant:
Thymoglobuline will be given as an intravenous infusion

- to prevent kidney transplant rejection: for 3 to 9 days after transplantation
- to treat kidney transplant rejection: for 7 to 14 days after transplantation.

Aplastic Anaemia:
Thymoglobuline will be given as an intravenous infusion every day for 5 days to treat aplastic anaemia.

Additional Medications

As part of your treatment, after kidney transplantation your doctor will usually give you other medicines in addition to Thymoglobuline. These medicines (immunosuppressants) also reduce your body's immune system response to the transplanted organ. These medicines may include some of the following: cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine and corticosteroids.

Approximately an hour before you receive Thymoglobuline, you may be given the following medications to reduce your chances of developing certain adverse reactions to Thymoglobuline:

- antihistamine
- corticosteriod
- antipyreytic (anti-fever) medicine.

If you receive too much (overdose)

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, immediately telephone your doctor, or the Poisons Information Centre on 13 11 26 or go to the Accident and Emergency Department at your nearest hospital.

While you are being treated with 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.

Tell all the doctors, dentists and pharmacists who are treating you that you are being given Thymoglobuline.

If you are about to be started on any new medicine, tell your doctor and

pharmacist that you are being given Thymoglobuline.

Things to be careful of

Be careful driving or operating machinery 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, light-headed, tired or drowsy.

Side effects

Thymoglobuline helps most people who have undergone a kidney transplant or have aplastic anaemia, but it may have unwanted side effects in some people.
All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Thymoglobuline.

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

- 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 or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Thymoglobuline. You may need urgent medical attention or hospitalisation.

Thymoglobuline may cause a temporary lowering of your infection-fighting white blood cells, which may make you more prone to catching infections. This may result in fever, chills, sore throat or mouth ulcers. Thymoglobuline may also cause a temporary lowering of your platelets which may make you more prone to blood clotting problems. This may cause you to bleed and bruise more easily.

Tell your doctor or nurse if you notice any of the following and they worry you:

- generally feeling unwell
- headaches
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise) nausea and vomiting
- fevers, rigors and or chills
- diarrhoea.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- dizziness, light-headedness
- flushing or redness of the skin
- infections
- high blood pressure.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed above may occur in some patients. Tell your doctor or nurse if you notice anything that is making you feel unwell.

After using Thymoglobuline

Storage

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.

Product description

What Thymoglobuline looks like

Thymoglobuline is a creamy white freeze dried powder supplied in a 10 mL glass vial.

AUST R 139787

Ingredients

Active ingredients:

Rabbit anti-human thymocyte immunoglobulin 5 mg/mL.

Other ingredients

- Glycine
- Sodium chloride
- Mannitol.

Supplier

In Australia this product is registered by:

Genzyme Australasia Pty Ltd.
Building D
12-24 Talavera Road
Macquarie Park, NSW 2113
Toll Free Number: 1800 818 806
Email:
medinfo.australia@sanofi.com

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