PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ATGAM® solution for infusion

Antithymocyte immunoglobulin (equine)

Sugar free

Read all of this leaflet carefully before you are given ATGAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ATGAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ATGAM is and what it is used for
2. What you need to know before you are given ATGAM
3. How to receive ATGAM
4. Possible side effects
5. How to store ATGAM
6. Contents of the pack and other information

1. What ATGAM is and what it is used for

ATGAM belongs to a group of medicines called immunosuppressants (anti-rejection medicines).

ATGAM is used in patients who are having a kidney transplant. It is used together with other medicines to stop your body's immune system from rejecting the new kidney.

ATGAM is also used in patients whose bodies have stopped producing enough new blood cells (aplastic

anaemia) and who are unsuitable for bone marrow transplants.

2. What you need to know before you are given ATGAM

ATGAM should not be administrated to you:

- if you are hypersensitive (allergic) to antithymocyte immunoglobulin (equine) or any of the other ingredients of ATGAM (listed in section 6).
- if you have had a severe reaction (e.g. anaphylactic reaction) during prior treatment with ATGAM or any other horse proteins (equine gamma globulins).

ATGAM has not been studied in pregnant and breastfeeding women. Your doctor will discuss the benefits and risks of using ATGAM in pregnancy and breastfeeding.

There is limited experience with the use of ATGAM in children.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Special care should be taken with ATGAM:

You should only be treated with ATGAM by a doctor who is experienced in giving treatments which reduce your immune response.

Treatment should take place in a hospital because of the need for hospital facilities and skilled personnel.

Treatment with ATGAM will be stopped if you experience a severe allergic reaction (anaphylaxis), or a severe reduction in the concentration of platelets (thrombocytopenia) or of white blood cells (leukopenia) in the blood.

Before treatment with ATGAM, skin testing may be performed to check if you are allergic to any of the ingredients of ATGAM. The results from the tests will help your doctor decide whether ATGAM can be given to you or not.

While on treatment with ATGAM you will be constantly monitored for the possibility of concurrent infection and severe allergic reaction (anaphylaxis).

It is possible that products developed from or purified with human blood components can carry infectious diseases. The procedures used for the collection of the blood components and the manufacturing of ATGAM are designed to reduce the risk of transmission. However, the possibility of passing on infection cannot be totally excluded.

Do not have any vaccination during or soon after treatment with ATGAM without first discussing it with your doctor or pharmacist, as it may be less effective because your immune system cannot respond to it.

Other medicines and ATGAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are receiving ATGAM with other medicines which suppress your immune system (such as corticosteroids), you must be carefully monitored as you may be more susceptible to infections.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

ATGAM has not been studied in pregnant and breastfeeding women. Your doctor will discuss the benefits and risks of using ATGAM in pregnancy and breastfeeding.

Driving and using machines

Given the potential side effects that may be experienced (e.g. dizziness, fits, confused state, fainting), caution should be taken when driving or using machinery while on ATGAM.

It is not always possible to predict to what extent ATGAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ATGAM affects them.

3. How to receive ATGAM

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself ATGAM. It will be given to you by a person who is qualified to do so.

ATGAM is administered into the vein via a drip.

Before you are given ATGAM, your doctor or health care provider should carry out a skin test to identify if you are at risk of an allergic reaction.

The dose and frequency will depend on what you are being treated for with ATGAM.

Patients with a kidney transplant will receive 15 mg/kg daily for 14 days, then every other day for 14 days. In total you will receive ATGAM on 21 days out of 28. Your first dose will be administered 24 hours before, or after the transplant.

Your doctor may decide to wait until there are signs that your body is rejecting the new kidney. In this case you will be given 10 to 15 mg/kg ATGAM every day for 14 days. You may then also be given ATGAM every other day for another 14 days. In total you could be given 21 doses of ATGAM.

If you are being treated for aplastic anaemia, you will receive 10 to 20 mg/kg daily for 8 to 14 days. You may then also be given ATGAM every other day up to a total of 21 doses.

Your doctor will tell you how long your treatment with ATGAM will last. Do not stop treatment early.

If you have the impression that the effect of ATGAM is too strong or too weak, tell your doctor or pharmacist.

If you receive more ATGAM than you should

Since a health care provider will administer ATGAM, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to receive ATGAM

Since a health care provider will administer ATGAM, it is unlikely that the dose will be missed.

If you miss a dose of ATGAM, tell your doctor or health care provider immediately.

4. Possible side effects

ATGAM can have side effects.

Not all side effects reported for ATGAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ATGAM, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Sudden signs of allergy such as rash, itching or hives on the skin (urticaria)
- Redness, swelling or blistering of the skin
- Swelling of the face, lips, tongue or other parts of the body
- Sudden shortness of breath or trouble breathing (dyspnoea)
- Fits (convulsions)

These are all very serious side effects. If you have them, you may have had a serious allergic (anaphylactic)

reaction to ATGAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Bleeding or bruising more easily than normal - this could be cause by a decreased level of platelets in the blood (thrombocytopenia)
- Infection - this could be caused by a decrease in different types of white blood cells (leukopenia, granulocytopenia* or neutropenia*)
- Swollen glands (lymphadenopathy)
- Headache
- Dizziness
- Fast or slow heart beat (tachycardia or bradycardia)
- Swollen or inflamed veins (particularly in the legs), blockage or blood clot in the vein (thrombophlebitis)
- High or low blood pressure (hypertension or hypotension)
- Nausea
- Vomiting
- Diarrhoea
- Stomach pain
- Aching muscles or joints (arthralgia)
- Back pain
- Fever or chills
- Chest pain
- Pain at the injection site
- Fluid retention (oedema)
- Clotting in the connection between an artery and a vein (arteriovenous fistula thrombosis)

Less frequent side effects

- Cold sores around the mouth or face (Herpes simplex)
- High blood sugar levels (hyperglycaemia)

- Agitation
- Inflammation of the brain (encephalitis)
- Tingling or decreased feeling or sensitivity, especially in the skin (paraesthesia)
- Blood clot in the artery leading from the kidney (renal artery thrombosis)
- Blockage in the veins of the pelvis (iliac vein occlusion)
- Fluid in or around the lungs (pulmonary oedema or pleural effusion)
- Spasm of the vocal cords (laryngospasm)
- Swelling of the mucous membranes in the mouth (stomatitis)
- Hiccups
- Skin rash, itchiness (pruritis)
- Night sweats
- Puffiness around the eyes (periorbital oedema)
- Skin condition where the top layer of skin detaches from the lower layers of the skin (toxic epidermal necrolysis)
- Protein in urine (proteinuria)
- Tiredness or weakness (asthenia)
- General feeling of being unwell (malaise)
- Abnormal kidney test results
- Abnormal liver test results
- Re-opening of wounds that have been stitched (wound dehiscence)

*Other side effects**

- Liver infection caused by a virus (viral hepatitis)
- An infection in the bloodstream (systemic infection) or in a particular area of the body (localised infection)
- Abnormal blood cell counts and platelets
- Inflammation in the blood vessels (vasculitis)
- Confused state or feeling disorientated
- Involuntary muscle movements (dyskinesia), or tremors

- Fainting (syncope)
- Heart failure
- A blood clot in a deep vein, usually in the legs (deep vein thrombosis)
- A hole or bleeding in the stomach or intestine (gastrointestinal perforation/haemorrhage)
- Repeatedly stopping breathing for a short periods of time (apnoea)
- Cough
- Nosebleeds (epistaxis)
- Pain in the abdomen
- Pain in the mouth or throat
- Pain between the ribs and hop (flank pain)
- Stiff muscles or muscle pain (myalgia)
- Pain in hands or feet
- Enlarged kidneys, kidney failure or a ruptured kidney
- Swelling or redness at the injection site
- Excessive sweating (hyperhidrosis)

*Side effects reported during post-marketing experience

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ATGAM.

5. How to store ATGAM

- Store all medicines out of reach of children.

The following information is intended for the health care provider who is responsible for the storage, handling, and disposal of ATGAM.

- Your hospital pharmacy will ensure the product is stored in a refrigerator at or below 2 - 8 °C, the ampoule is kept in the outer carton in order to protect from light and that it is used before the expiry date printed on the label.
- Diluted solution should be kept at room temperature (20 - 25 °C). The solution should be used within 24 hours (including infusion time).

6. Contents of the pack and other information

What ATGAM contains

- Each 1 mL of ATGAM contains 50 mg of the active substance antithymocyte immunoglobulin (equine).
- The other ingredients are glycine and water for injection. Hydrochloric acid and/or sodium hydroxide may be present for pH adjustment.

What ATGAM looks like and contents of the pack

ATGAM is a transparent to slightly opalescent aqueous protein solution. It may appear colourless to faintly pink or brown and is nearly odourless. It may develop a slight granular or flaky deposit during storage.

ATGAM solution for infusion is available in 5 mL ampoules in cartons of 5 ampoules.

Holder of Certificate of Registration

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