

Atgam® Injection

Equine Antithymocyte immunoglobulin

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before being treated with ATGAM.

This leaflet answers some common questions about ATGAM. It does not contain all the available information and 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 treating you with ATGAM against the expected benefits it will have for you.

Ask your doctor if you have any concerns about being given this medicine.

Keep this leaflet even after your treatment with ATGAM is finished.

You may need to read it again.

What ATGAM 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 helps to stop your body's immune system from rejecting the new kidney.

How ATGAM works

ATGAM works by lowering certain cells within your immune system which are likely to attack your transplanted kidney.

Your doctor may prescribe ATGAM for another purpose.

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

Before being treated with ATGAM

Always talk to your doctor if you have concerns or questions about your treatment.

When ATGAM must not be used

ATGAM must not be used if you are allergic to equine antithymocyte immunoglobulin or other horse proteins (equine gamma globulins).

ATGAM must not be used if the expiry date (EXP) on the carton or ampoule label has passed. Damaged or leaking ampoules should not be used.

Before treatment 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.

Your doctor will usually give you other medicines when you are given ATGAM. These medicines are also used to reduce your immune response to the new kidney.

It is possible that products developed from human blood can carry infectious diseases like viral hepatitis and AIDS.

You should tell your doctor if:

- You have previously been treated with ATGAM.

Before being treated with ATGAM, your doctor should do a skin test to see if you are likely to have an allergic reaction to ATGAM.

Pregnancy

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

Breastfeeding

Do not breastfeed if you are being treated with ATGAM. Ask your doctor if you want more information.

Children

The use of ATGAM in children is limited. It has been used in a small number of children who have had kidney, liver or bone marrow transplants and aplastic anaemia (anaemia due to the absence of bone marrow).

Taking other medicines

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

How ATGAM is given

How ATGAM is given

ATGAM will be given to you by your doctor usually after skin testing. It is diluted and given by slow infusion into a vein over a period of at least 4 hours.

You will be watched all the time in case you have an allergic reaction to ATGAM. If you have an allergic reaction, treatment with ATGAM will be stopped.

You may need to have regular checks for new infections.

How much is given

The recommended dose is 15 mg/kg every day for 14 days. Then on every other day for 14 days. A lower dose may be given in the elderly. In total you will receive ATGAM on 21 days out of 28. Your first dose will usually be given within 24 hours of your kidney transplant, either the day before or the day after.

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 receive too much (overdose)

ATGAM will be given under medical supervision so an overdose is unlikely.

While you are being treated with ATGAM

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 response to ATGAM.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with ATGAM.

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are being treated with ATGAM.

Tell your doctor immediately if you become pregnant while being treated with ATGAM.

Things to be careful of

Be careful driving or operating machinery until you know how ATGAM affects you.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with ATGAM.

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

Do not be alarmed by this list of side effects.

You may not experience any of them.

Very common side effects (occurring in 15% or more of patients):

- fever, chills, low white blood cell count (which will lower your resistance to infection)
- blood clotting problems, low platelet count
- skin rash, itchiness.

Treatment with ATGAM should be stopped if your white blood cell or platelet count drops severely, or you have severe blood clotting problems.

Common side effects (occurring in 1 to 15% of patients):

- painful joints, chest and/or back pain, pain at the site of injection
- diarrhoea, nausea, vomiting
- breathlessness
- headache
- slow heart rate, low blood pressure, high blood pressure
- night sweats
- blood clots in veins
- infections
- sore mouth.

Rare side effects (occurring in less than 1% of patients) that may require immediate medical attention include:

- severe allergic reaction (anaphylaxis) which may cause any of the following symptoms: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; feeling lightheaded or dizzy; skin rash, itching, hives or redness of the skin; pain in the chest, back or between the ribs and hip.
- possible inflammation of the brain
- seizure
- skin condition where the top layer of skin detaches from the lower layers of the skin all over the body
- rupture or failure of the kidney.

Some possible side effects of ATGAM, such as abnormal liver or kidney function, can only be detected by your doctor.

Not all side effects are listed here. You may wish to discuss these with your doctor if you are concerned.

Tell your doctor as soon as possible if you experience any side effects, including any effects not listed above.

After treatment with ATGAM

Storage

ATGAM will normally be stored in a hospital. It should be stored at 2°C to 8°C and should not be frozen.

Disposal

The hospital will dispose of used or damaged ampoules of ATGAM.

Product Description

What ATGAM looks like

ATGAM is a sterile, transparent to milky solution which is colourless or faintly pink or brown. It may develop a slight granular or flaky deposit during storage. It is supplied in 5 mL ampoules. Each ampoule is for single use only.

Ingredients

The active ingredient in ATGAM is equine antithymocyte immunoglobulin. There are 250 mg equine antithymocyte immunoglobulin in the 5 mL ampoule.

Other ingredients are glycine, Water for Injections, sodium hydroxide and hydrochloric acid. ATGAM does not contain any preservatives.

Supplier

ATGAM is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

ATGAM is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998 Auckland

Toll Free Number: 0800 736 363

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