

ATGAM[®] INJECTION

Antithymocyte Globulin - equine

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 taking this medicine.

Consider keeping this leaflet even after your treatment with ATGAM is finished. You may need to read it again.

What ATGAM is used for

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. ATGAM works by suppressing your immune system.

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

Some information is provided below. **However, 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 antithymocyte globulin - equine 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
- You are taking any other medicines, including medicines that you buy without a prescription.

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.

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).

Treatment with ATGAM

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, using an inline filter, 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.

Dose

The recommended dose is 15 mg/kg every day for 14 days. Then on every other day for 14 days. 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.

In case of overdose

Talk to your doctor if you are concerned that you have received or are receiving too much ATGAM.

Side effects

ATGAM, like all other medicines, may cause unwanted side effects.

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, low blood pressure, high blood pressure
- night sweats
- blood clots in veins
- infections
- sore mouth

Uncommon/Rare side effects (occurring in <1% of patients)

- severe allergic reaction (anaphylaxis)
- possible inflammation of the brain

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

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

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

Used or damaged ampoules of ATGAM should be disposed of by incineration.

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 millilitre (mL) ampoules. Each ampoule is for single use only.

Ingredients

The active ingredient in ATGAM is antithymocyte globulin - equine. There are 250 mg antithymocyte globulin-equine 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
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114

Toll Free Number: 1800 675 229

ATGAM is supplied in
New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland

Toll Free Number: 0800 736 363

Australian Registration Number

AUST R 12282

This leaflet was prepared in March 2004.

®Registered Trademark

©Copyright 2002