Read all of this leaflet carefully before you are given this medicine because it contains important information for you. Keep it, you may need to read it again.

Tell your doctor immediately if you notice:
- A raised itchy rash
- Difficulty in breathing
- Stormy stomach
- Swelling of the face, tongue or throat

Sometimes, receiving a Thymoglobuline infusion may cause the following additional side effects. You should tell your doctor as soon as possible if you have any of the following:
- Dizziness, feeling faint
- Tiredness
- Joint pain
- Nausea
- Feeling or being sick

Common side effects (may affect more than 1 in 100 people):
- Low white blood cell count, low platelet count
- Fever
- Infection

These side effects may be mild and go away on treatment with other medicines. They may also be reduced by changing the dose of Thymoglobuline or increasing the period of time over which it is given.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse before taking this medicine. This is because Thymoglobuline should not be given to pregnant women unless it is absolutely necessary as the effects are unknown.

If you are allergic to animal products, ask your doctor or nurse before taking this medicine. This is because Thymoglobuline contains rabbit anti-human thymocyte immunoglobulin.

If you are receiving Thymoglobuline with other medicines which suppress your immune system, you may be more susceptible to infections.

Talk to your doctor if you are concerned about any of these side effects or if there is anything you do not understand.

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5. How to store Thymoglobuline

Your medicine will be stored in a hospital by a doctor or nurse, out of the sight and reach of children.

The unopened vials of Thymoglobuline will be stored in a refrigerator (2 – 8 °C).

6. Contents of the pack and other information

What Thymoglobuline contains

The active substance is: 25 mg of rabbit anti-human thymocyte immunoglobulin.

The other ingredients are: mannitol, glycine, sodium chloride (salt).

Thymoglobuline may also contain residues of polysorbate, from the manufacturing process.

What Thymoglobuline looks like and contents of the pack

Thymoglobuline is supplied in a glass vial containing a white powder.

Before it is used it is mixed with 5 millilitres (ml) of sterile water to make a liquid. Each millilitre (ml) contains 5 mg of rabbit anti-human thymocyte immunoglobulin. This liquid is then mixed with a sodium chloride or glucose solution so that it can be given slowly (infused) into your bloodstream through a plastic tube (catheter) in a large vein.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Genzyme Europe B.V.
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands

Manufacturer
Genzyme Polyclonals S.A.S.
23 boulevard Chambaud de la Bruyère
69907 Lyon, France.

Genzyme Ireland Ltd
IDA Industrial Park
Old Kilmeaden Road
Waterford, Ireland

Local representative:

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Email:UK-medicalinformation@sanofi.com

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San Gwann SGN 2003, Malta
Tel: +356 21493022
email:PharmacovigilanceMalta@sanofi.com

Marketing Authorisation numbers:

UK: PL 12375/0021
Ireland: PA 611/3/1/1
Malta: MA 596/002/01

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Thymoglobuline 25 mg powder for solution for infusion
Malta: Thymoglobuline 25 mg powder for solution for infusion
Slovenia: Thymoglobuline 25 mg, powder for solution for infusion
UK: Thymoglobuline 25 mg powder for solution for infusion

This leaflet was last revised in 11/2018
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IDA Industrial Park, Old Kilmeaden Road, Waterford, Ireland