

PATIENT INFORMATION LEAFLET  
**HUMAN TETANUS  
 IMMUNOGLOBULIN**  
**100 IU/mL SOLUTION FOR INJECTION**



**Please read all of this leaflet carefully before using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Is this leaflet hard to see or read? Phone +44 (0)20 8957 2200.

**In this leaflet:**

1. What Human Tetanus Immunoglobulin is and what it is used for
2. Before you are given Human Tetanus Immunoglobulin
3. How you are given Human Tetanus Immunoglobulin
4. Possible side effects
5. How to store Human Tetanus Immunoglobulin
6. Further information

### 1. WHAT HUMAN TETANUS IMMUNOGLOBULIN IS AND WHAT IT IS USED FOR

This product is a solution containing a large quantity of tetanus antibodies. It is prepared from blood plasma from screened donors and virally-inactivated during manufacture. It is used to protect you against tetanus and is normally given with tetanus vaccine. Your doctor will explain further why this medicine has been given to you.

This product is usually given to you if:

- you have not had previous vaccination to tetanus, or have not been properly vaccinated, or do not know whether you have been vaccinated to tetanus but may have recently been exposed to tetanus because you have been wounded e.g by a cut, bite or pierced by a foreign body
- you have had a full course of vaccination to tetanus but have recently had a severe injury with a high risk of being infected by tetanus germs

Human Tetanus Immunoglobulin is given by injection into a muscle (intramuscular) such as the buttock or thigh. Your doctor or nurse will give you the injection.

### 2. BEFORE YOU ARE GIVEN HUMAN TETANUS IMMUNOGLOBULIN

You must not be given this medicine if you are:

- **suffering** from any blood disorders which interfere with clotting
- **allergic** to any of the ingredients in this product (see Section 6 'Further Information' for a list of these).

**Special care must be taken with Human Tetanus Immunoglobulin if you:**

- **develop an allergic reaction** (see Section 4 'Possible Side Effects' for a list of these). If you suffer from any of these, or just feel unwell, tell your doctor.
- **suffer from a blood disorder**. Inform your doctor before this medicine is injected. Your doctor or nurse may inject this product just under the skin under these circumstances.
- **have had any vaccinations recently** or know you are about to have any vaccinations. Tell your doctor if this is the case.
- **have had this product recently** as it may give misleading results if you have a **blood test**. Tell your doctor if this is the case.

#### Taking other medicines

Please tell your doctor if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

This solution for injection must not be mixed with other medicinal products for injection.

Your doctor will advise you about any vaccinations you may need in addition to giving you this product.

#### Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are breastfeeding before this medicine is injected.

#### Driving and using machines

There are no known effects of this product on your ability to drive or operate machinery.

### 3. HOW YOU ARE GIVEN HUMAN TETANUS IMMUNOGLOBULIN

This product must always be injected by a doctor or nurse. Human Tetanus Immunoglobulin must never be injected into a vein; it must be injected slowly into a large muscle such as the buttock or thigh.

#### Doses

As a precaution 250 IU will be given (this is the contents of one vial) and this may be increased to 500 IU (two vials) if your wound is more serious.

Your doctor will advise you on the dose for you.

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Project Name:		Human Tetanus PIL UK STDNL6			
Contact:	Laura Ambrose	Client Order No.	P43953		
Date:	28/09/2018	Proof No.	3		
Operator:	Hema Joshi	Doc. Size:	90 x 290mm		

#### 4. POSSIBLE SIDE EFFECTS

As with all medicines, Human Tetanus Immunoglobulin may cause side effects, although not everybody gets them.

There may be some short term discomfort at the site of injection. Very rarely a hardened area may develop where the injection was given.

The following may also occur after injection:

chest pain, shortness of breath, shaking,  
dizziness, swelling of the face, coating of the tongue,  
mouth ulcers, joint pains, slight fever.

If you get any of these or continuous pain, itching, rash or any other reaction or just feel unwell, you must tell your doctor.

#### Please note

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include: – careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, – the testing of each donation and pools of plasma for signs of virus/infections, – the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections. The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the nonenveloped hepatitis A and parvovirus B19 viruses. Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

#### 5. HOW TO STORE HUMAN TETANUS IMMUNOGLOBULIN

- **Keep out of the reach and sight of children.**
- You should store the medicine in its carton to protect it from light, in the refrigerator (2-8°C). **Do not freeze.** Short periods (up to one week) of storage at room temperature (25°C), in the dark, will not damage the product.
- Do not use the medicine after the expiry date which is printed as "EXP" on the containers (the expiry date refers to the last day of the month stated).
- **Do not use** the medicine if it is cloudy or any small bits can be seen in it.

#### Disposal

After injection of the correct dose, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers. Medicines should not be disposed of via wastewater or household waste.

#### 6. FURTHER INFORMATION

##### What Human Tetanus Immunoglobulin contains

The **active** substance is immunoglobulin containing a specifically high concentration of antibodies (not less than 100 IU/mL) to the poison produced by the germ which causes tetanus.

The **other** ingredients are: glycine, sodium chloride, sodium acetate and a small quantity of sodium hydroxide.

##### What Human Tetanus Immunoglobulin looks like and the contents of the pack

Human Tetanus Immunoglobulin is a clear to slightly cloudy, colourless to pale yellow sterile solution, available as single dose vials containing 250 IU in glass vials. These vials are closed with a synthetic rubber stopper, held on by an aluminium ring and flip off cover.

##### Marketing Authorisation Holder and manufacturer

Bio Products Laboratory Limited, Dagger Lane, Elstree, Hertfordshire, WD6 3BX, United Kingdom

##### Marketing Authorisation Number PL 08801/0011

For further information or if you have any questions about the use of this product, please contact BPL via the Marketing Department at the address above or through [info@bpl.co.uk](mailto:info@bpl.co.uk).

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**bpl**

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