

## **Package leaflet: Information for the patient**

### **Human Tetanus Immunoglobulin 100 IU/ml solution for injection**

human tetanus immunoglobulin

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or healthcare professional.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Human Tetanus Immunoglobulin is and what it is used for
2. What you need to know before you use Human Tetanus Immunoglobulin
3. How to use Human Tetanus Immunoglobulin
4. Possible side effects
5. How to store Human Tetanus Immunoglobulin
6. Contents of the pack and other information

#### **1. What Human Tetanus Immunoglobulin is and what it is used for**

Human Tetanus Immunoglobulin contains the active ingredient human tetanus immunoglobulin. It is prepared from blood plasma from screened donors.

It is used to protect you against tetanus following an injury 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.

#### **2. What you need to know before you use Human Tetanus Immunoglobulin**

##### **Do not use Human Tetanus Immunoglobulin**

- If you are allergic to human tetanus immunoglobulin, other human immunoglobulins or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, nurse or healthcare professional before you are given Human Tetanus Immunoglobulin.

Special care must be taken with Human Tetanus Immunoglobulin if:

- you develop an allergic reaction – see section 4, ‘Possible side effects’, for signs of an allergic reaction
- you have a blood disorder affecting bleeding or clotting. Inform your doctor before this medicine is injected. Your doctor or nurse may inject this product just under the skin under these circumstances
- any of the following applies to you, as using this medicine may increase the risk of blood clots:

- high blood pressure
  - diabetes, with problems with your veins or arteries or a previous blood clot
  - low blood volume, which may be caused by severe dehydration, diarrhoea, vomiting or blood loss
  - a period of sitting or lying still for a long period, e.g. hospitalisation or a long flight
- See section 4, 'Possible side effects', for signs of a blood clot.

Tell your doctor if you have had any vaccinations recently or know you are about to have any vaccinations. This medicine may affect the way the vaccination works.

If you have a blood test, tell your doctor you have received this product recently as it may give misleading results.

### **Viral safety**

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 non-enveloped hepatitis A virus 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.

It is strongly recommended that every time you receive a dose of Human Tetanus Immunoglobulin, the name and batch number of the product are recorded to maintain a record of the batches used.

### **Children and adolescents**

The listed warnings and precautions apply to both adults and children.

### **Other medicines and Human Tetanus Immunoglobulin**

Tell your doctor, nurse or healthcare professional if you are taking, have recently taken, or might take 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, breast feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### **Driving and using machines**

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

### **Human Tetanus Immunoglobulin contains sodium**

This medicinal product contains less than 1 mmol sodium (23 mg) per 250 IU dose, i.e. essentially 'sodium free'.

### **3. How to use Human Tetanus Immunoglobulin**

Your doctor, nurse or healthcare professional will inject Human Tetanus Immunoglobulin into a muscle. They will decide how much to give you.

#### **If you use more Human Tetanus Immunoglobulin than you should**

If you are given more Human Tetanus Immunoglobulin than recommended, your doctor, nurse or healthcare professional may carry out some blood tests. It is not known what effects an overdose would have.

If you have any further questions on the use of this medicine, ask your doctor, nurse or healthcare professional.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For some people there is an increased risk of this medicine causing serious allergic reactions or blood clots. See section 2, 'What you need to know before you use Human Tetanus Immunoglobulin' for more information. Speak to your doctor before using this medicine if you have any concerns.

Signs of a serious allergic reaction include:

- Difficulty breathing or swallowing
- Swollen lips, tongue, face or throat
- Suddenly feeling dizzy or fainting

If you notice any of these, stop using this medicine and tell your doctor immediately, or go to your nearest hospital emergency department. You may need medical attention.

#### Other possible side effects

Frequency not known (cannot be estimated from the available data)

- Headache
- Feeling dizzy
- Shaking
- Increased heart rate
- Low blood pressure
- Feeling sick
- Being sick
- Pain/swelling/change in appearance of tongue
- Mouth ulcers
- Skin rash
- Redness or itching of the skin
- Joint pain
- Fever
- Chills
- Generally feeling unwell
- Reactions at the site of injection such as swelling, warmth, pain, redness, itching or rash and hardening of the skin

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme: [www.mhra.gov.co.uk/yellowcard](http://www.mhra.gov.co.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Human Tetanus Immunoglobulin**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the containers after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

A short period (up to one week) of storage at room temperature (up to 25°C), in the unopened package will not damage the product.

Keep the vial in the outer carton in order to protect from light.

Do not use this medicine if you notice the solution is cloudy or has deposits.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Human Tetanus Immunoglobulin contains**

- The active substance is human tetanus immunoglobulin.
- The excipients are: sodium chloride, glycine, sodium acetate trihydrate, hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

Each ml of solution contains at least 100 IU of human tetanus immunoglobulin. The volume required to give the stated dose is printed on the vial label.

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

Human Tetanus Immunoglobulin is a clear to slightly opalescent, colourless to pale yellow sterile solution, available as single dose vials containing 250 IU in glass vials with a closure to prevent tampering.

### **Marketing Authorisation Holder**

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