**Tetagam-P 250 IU Solution for Injection**

Human Tetanus Immunoglobulin

**What is this medicine used for?**Tetagam-P is an injection solution containing the protein "human tetanus immunoglobulin" (human tetanus antibody). Immunoglobulins are antibodies that naturally occur in human blood and protect you against infections. Specifically, this medicine contains immunoglobulin G (= IgG), an antibody that works against toxins produced by the bacterium Clostridium tetani, which cause tetanus. The maximum IgA concentration is 6 g/l.

Tetanus immunoglobulin is an antibody that is effective against toxins produced by the tetanus bacterium. The so-called "tetanus toxin" can cause severe acute muscle spasms in humans after a wound infection (this serious disease is called tetanus). The antibodies present in the product neutralize the harmful effects of the toxin. In this way, the toxin is rendered harmless, and tetanus is prevented or treated (known as passive immunization).

**When should you not use this medicine or take extra caution?**

When should you not use this medicine:

* If you are allergic (hypersensitive) to immunoglobulins or any of the other ingredients of Tetagam-P
* Administration of Tetagam-P should be immediately stopped in case of an allergic reaction. The product is not suitable for intravenous administration (administration into a vein).

**When should you take extra caution with this medicine?**Tetagam-P contains a small amount of IgA. In patients with no immunoglobulin A (IgA deficiency) and antibodies against immunoglobulin A, Tetagam-P can induce a severe hypersensitivity reaction (anaphylactic reaction). An anaphylactic reaction can also occur in patients who did not show hypersensitivity after previous use of blood or blood products.

If you have IgA deficiency with antibodies against immunoglobulin A or if you have previously shown hypersensitivity to blood or blood products, this product should only be administered if absolutely necessary. Moreover, the administration of Tetagam-P should be performed under careful medical supervision. You will be observed by a doctor or nurse for at least 20 minutes after administration. For information on side effects, please refer to section 4 of this leaflet.

**Do you use any other medications?**Tetagam-P should not be mixed with other medications. If you are using or have recently used any other medications or if there is a possibility that you will use other medications in the near future, please inform your doctor or pharmacist.

**Vaccination**Inform your doctor if you have been vaccinated in the past 3 to 4 weeks or if you will be vaccinated soon (within 3 months after receiving Tetagam-P). Tetagam-P may weaken the effectiveness of vaccines such as measles, rubella, mumps, and chickenpox. After using Tetagam-P, you should wait at least three months before receiving any of these vaccines. In the case of measles, this weakening effect can last up to 5 months.

**Impact on blood tests**The use of Tetagam-P may affect the results of certain blood tests.

**Food, drink, and alcohol**There are no known effects of food, drink, and alcohol on the use of Tetagam-P.

**Pregnancy and breastfeeding**The use of Tetagam-P during pregnancy or while breastfeeding has not been studied. The use of immunoglobulins, such as Tetagam-P, during pregnancy or while breastfeeding has not shown any harmful effects so far. Immunoglobulins are transferred to newborns through breast milk and contribute to the defense of the newborn. Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please consult your doctor or pharmacist before using this medicine.

**Driving and using machinery**No effects on driving ability and the ability to operate machinery have been observed.

**Special warnings and precautions for use**Certain measures need to be taken with medications made from human blood or plasma to prevent transmission of infections to the patient. These measures include:

* Careful selection of blood and plasma donors to exclude donors who may be carriers of infection
* Testing each donation or plasma pool for viruses or other infections
* Applying production steps to these products that can inactivate or remove viruses.

Despite these measures, the risk of transmission of infections cannot be completely eliminated when administering medications prepared from human blood or plasma. This also applies to unknown or emerging viruses or other pathogens.

The measures taken are considered effective against enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus, and the non-enveloped virus hepatitis A virus. The measures may have limited value for non-enveloped viruses such as parvovirus B19.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections, possibly because the product contains antibodies that protect against these infections.

It is strongly recommended to record the product's name and batch number with each administration of Tetagam-P to keep track of the batches used.

**Excipients:** The product contains the following excipients: glycine, sodium chloride, HCl or NaOH (in small quantities to adjust the pH value), and water for injections.

**How to use this medicine?**

**Administration**Administration of Tetagam-P should be done by a doctor. Tetagam-P should be injected into the muscle (intramuscularly). The injection is usually given in the upper arm or buttock.

The product should not be too cold during administration. It is recommended to warm the product to body temperature before administration.

When administering a large dose (more than 2 ml for children and more than 5 ml for adults), it is recommended to divide the doses into multiple injection sites.

Tetagam-P provides short-term protection against tetanus. This involves an injection of antibodies against the toxin produced by the tetanus bacterium (passive immunization).

Long-term protection against tetanus is only achieved after administration of tetanus vaccine. In this case, the human body itself produces antibodies after the introduction of inactivated tetanus toxin (active immunization). Tetagam-P and tetanus vaccine can be administered simultaneously. Tetagam-P provides protection (immunity) against tetanus disease, while the body builds long-term protection against this disease through the administration of tetanus vaccine. The tetanus vaccine contains inactivated tetanus toxin, which stimulates the body to produce antibodies against this toxin, known as active immunization.

Whether you receive tetanus vaccine (active immunization) and/or Tetagam-P (passive immunization) depends on the extent to which you have already been vaccinated against tetanus (vaccination status).

If both active and passive immunization are required, the immunoglobulin and the vaccine should be administered at different injection sites.

In the case of children: if your child is still participating in the vaccinations of the National Immunization Program, separate tetanus vaccine is never given after an injury. Instead, the next scheduled vaccination containing tetanus toxoid from the National Immunization Program is administered.

After complete recovery from tetanus disease, you should be fully vaccinated since having tetanus does not provide protection (immunity) against a recurrence of the disease.

If you have any further questions about the use of this medicine, ask your doctor.

In patients with a predisposition to spontaneous, sometimes long-lasting bleeding, the product can be administered subcutaneously (under the skin). The efficacy of the product cannot be guaranteed in this case.

**Dosage**

Prophylaxis after injuries where there is a risk of tetanus:

* 250 IU (1 pre-filled syringe of Tetagam-P), unless the risk is considered very high

The dose can be doubled to 500 IU in the following cases:

* Infected wounds where appropriate medical treatment cannot be administered within 24 hours

Deep or contaminated wounds with tissue damage and impaired oxygen supply, and injuries caused by a foreign body (such as bites, puncture wounds, and gunshot wounds)

Administration is meaningful for up to three weeks after the injury.

Clinical manifest tetanus: once the diagnosis is established, 3000 IU (12 pre-filled syringes of Tetagam-P)

**Possible Side Effects**Like any medicine, this medicine can have side effects, although not everyone experiences them.

Allergic reactions are rare. In the case of a severe hypersensitivity reaction (anaphylactic shock), the administration should be immediately stopped and the reaction should be appropriately treated.

The following side effects are possible: pain/tenderness, swelling, redness, hardening, warmth, itching, and skin rash at the injection site.

In rare cases, the following may occur: fever, nausea, vomiting, low blood pressure, accelerated heart rate (tachycardia), malaise, chills, hypersensitivity reactions, headache, joint pain, skin reaction, itching, and redness of the skin.

The risk of transmitting pathogens through the use of a blood product is extremely low.

**How to store this medicine?**

* Store in the refrigerator (2°C - 8°C). Do not freeze.
* Keep the pre-filled syringe in the outer packaging to protect it from light.
* Keep out of sight and reach of children.
* Do not use Tetagam-P after the expiry date stated on the box.
* Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help to protect the environment.