CSL Behring

PACKAGE INSERT

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tetagam® P

Solution for injection for intramuscular use

Active Ingredient:
Human tetanus immunoglobulin

PHARMACOTHERAPEUTIC GROUP

Immune sera and immunoglobulins, human tetanus immunoglobulin, ATC-code: J06B B02

THERAPEUTIC INDICATIONS

Postexposure prophylaxis
Immediate prophylaxis after tetanus prone injuries in patients
- not adequately vaccinated
- whose immunisation status is not known with certainty
- with severe deficiency in antibody production

Therapy of clinically manifest tetanus
Tetanus immunoglobulin should always be administered in conjunction with an active tetanus vaccination unless there are contraindications or confirmation of adequate vaccination.

WHO guidelines and other official guidance regarding the use of human tetanus immunoglobulin for intramuscular use should be observed.

CONTRAINDICATIONS

Known hypersensitivity to any of the components of the product.
Known hypersensitivity to human immunoglobulins.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Do not inject intravascularly! Ensure that Tetagam P is not administered into a blood vessel because of the risk of shock.
True hypersensitivity reactions are rare. Tetagam P contains a small quantity of IgA. Individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of blood components containing IgA. The physician must therefore weigh the benefit of treatment with Tetagam P against the potential risks of hypersensitivity reactions.
Rarely human tetanus immunoglobulin can induce a fall in blood pressure with anaphylactic reactions, even in patients who had tolerated previous treatment with normal human immunoglobulin.
Therapeutic measures depend on the nature and severity of the event.
The current medical standards for shock treatment are to be observed.
Patients should be observed for at least 20 minutes after administration of Tetagam P.
Particularly in cases of inadvertent i.v. injection, patients should be observed for longer term (at least 1 hour) after administration.

Important information about some of the ingredients of Tetagam P
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

Virus safety
Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/ removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV, and for the non-enveloped viruses HAV and parvovirus B19.
There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.
It is strongly recommended that every time that Tetagam P is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Pregnancy and lactation
The safety of Tetagam P for use in human pregnancy has not been established in controlled clinical trials. Long lasting clinical experience with immunoglobulins does indicate that no harmful effects on the course of pregnancy, on the foetus or the neonate are to be expected.

Effects on ability to drive and use machines
No effects on ability to drive and use machines have been observed.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

Vaccinations with live attenuated virus vaccines
Immunoglobulin administration may impair the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella vaccines for a period of up to three months.
After administration of Tetagam P an interval of at least three months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to five months. Therefore, patients receiving measles vaccine should have their antibody status checked.

Interference with serological testing
It has to be considered that when serological test results are interpreted, the transitory rise of passively transferred antibodies after immunoglobulin injection may result in misleading positive test results.
Passive transmission of antibodies to erythrocyte antigens, e.g., A, B and D may interfere with some serological tests for red cell allo-antibodies (e.g. Coombs test).

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products, diluents or solvents.

POSOLOGY AND METHOD OF ADMINISTRATION

Children and adults are to receive the same dose.

Posology
Prophylaxis of tetanus prone wounds
250 IU unless the risk is thought to be extremely high.
The dose may be increased to 500 IU in case of:
- infected wounds where surgically appropriate treatment cannot be achieved within 24 hours
- deep or contaminated wounds with tissue damage and reduced oxygen supply, as well as foreign-body injury (e.g., bites, stings or shots)
- burns, congelations
- tissue necrosis
- septicaemic abortion
- adults weighing more than the average.

In case of extensive burns it is advisable to administer a second injection of 250 IU Tetagam P after the exsudative phase of the burn has subsided (about 36 hours after onset of the burn).

Therapy of clinically manifest tetanus
Single doses of 3,000 to 6,000 IU (in combination with other appropriate clinical procedures). Regarding frequency, interval of injection and duration of therapy repeated doses depend on the clinical picture.

Method of administration
Tetagam P should be administered via the intramuscular route.
Do not use solutions which are cloudy or contain residues (deposits/particles).
Tetagam P is a ready for use solution and should be administered at body temperature.
If comparatively large total volumes are required, it is advisable to administer them in divided doses at different sites. This applies in the case of doses above 2 ml for children up to 20 kg bw and doses above 5 ml for persons above 20 kg bw.
In case of simultaneous vaccination the immunoglobulin and the vaccine should be administered at contralateral sites of the body.
In the presence of a severe coagulation disorder, in the case of which intramuscular injections are contraindicated, Tetagam P may be given subcutaneously (under the skin) for prophylaxis. Afterwards the injection site should be compressed with a swab. However, it should be noted that there are no clinical efficacy data to support administration by the subcutaneous route.
For acute therapy, if intramuscular administration is not clinically appropriate, an alternative intravenous product may be used.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

UNDESIRABLE EFFECTS

If you experience reactions which are not mentioned in this package insert, please inform your doctor or pharmacist.

In rare cases (≥ 1/10,000 and < 1/1,000) the following adverse reactions may occur:
- ***Immune system disorders***
  Allergic reactions including fall in blood pressure, dyspnoea, cutaneous reactions, in isolated cases reaching as far as anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration of immunoglobulins.
- ***Generalized reactions***
  Chills, fever, headache, malaise, nausea, vomiting, arthralgia and moderate back pain.
- ***Heart and vascular disorders***
  Cardiovascular reactions particularly if the product is inadvertently injected intravascularly.
- ***Local reactions at the injection site***
  Local pain, tenderness or swelling.

For safety with respect to transmissible agents, see section "Special warnings and precautions for use" subsection "Virus safety".

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

STORAGE AND STABILITY

Tetagam P is to be stored at +2 °C to +8 °C (refrigerator). Do not freeze!
Keep container in the outer carton in order to protect its contents from light.
Tetagam P must not be used after the expiry date given on the pack and container.
Once the container has been opened the contents have to be used immediately.
Keep out of the reach and sight of children!
Any unused product or waste material should be disposed of in accordance with local requirements.

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active ingredients

Human protein		100 – 170 mg
thereof immunoglobulin	at least	95 %
with antibodies to tetanus toxin	at least	250 IU

Other ingredients
Aminoacetic acid (glycine), sodium chloride, HCl or NaOH (in small amounts for pH adjustment), water for injections

PHARMACEUTICAL FORM AND PRESENTATIONS

Pharmaceutical form
Solution for injection for intramuscular use.
Tetagam P is a clear solution. The colour can vary from colourless to pale-yellow up to light brown during shelf life.

Presentations
Pack with 1 prefilled syringe with 1 ml
Pack with 10 prefilled syringes with 1 ml
Pack with 1 prefilled syringe with 2 ml
Not all pack sizes may be marketed.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Germany

DATE OF LAST REVISION

November 2014