TETANUS GAMMA 250 I.U.
Solution for injection, 2 ml vial
TETANUS GAMMA 500 I.U.
Solution for injection, 2 ml vial
TETANUS GAMMA 250 I.U.
Solution for injection, 2 ml pre-filled syringe
TETANUS GAMMA 500 I.U.
Solution for injection, 2 ml pre-filled syringe
J06BB02 Human tetanus immunoglobulin
for intramuscular use, virus inactivated with solvent/detergent method

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

1 ml of solution for injection contains:

Proteins	mg 100 - 180
of which human immunoglobulins not less than	90 %
with tetanus toxin antibodies (according to the presentation)	125 - 250 I.U.

List of excipients

Glycine, Sodium chloride, Water for injections.

PHARMACEUTICAL FORM

Solution for injection containing immunoglobulins, mainly immunoglobulin G (IgG), with 250 I.U. or 500 I.U. of active ingredient.
2 ml of solution for injection with tetanus toxin potency of 250 I.U. or 500 I.U. in according to the presentation, in vial with pierceable rubber stopper or in pre-filled syringe.

PHARMACOTHERAPEUTICAL CATEGORY

Human tetanus immunoglobulin.

HOLDER OF THE MARKETING AUTHORISATION

Kedrion S.p.A. - Loc. Ai Conti, 55020 Castelvecchio Pascoli, Barga (Lucca), Italy.

PRODUCED AND CONTROLLED BY:

a) vial with pierceable rubber stopper with solution for injection (250 I.U. and 500 I.U.)
Kedrion S.p.A. - 55027 Bolognana, Gallicano (Lucca),Italy and also Hardis S.p.A. - S.S. 7 bis Km 19,5, S. Antimo (Naples), Italy.

b) pre-filled syringe with solution for injection (250 I.U. and 500 I.U.)
Hardis S.p.A. - S.S. 7 bis Km 19,5, S. Antimo (Naples), Italy.

THERAPEUTIC INDICATIONS

a) Prophylaxis of tetanus in individuals with recent injuries that might be contaminated with tetanus spores and who have not been vaccinated in the previous 10 years or whose prior vaccination regimen was incomplete or is unknown.

b) Treatment of clinically manifest tetanus.

CONTRAINDICATIONS

The lethal risk associated with tetanus rules out any possible contraindications (see warnings listed below).

SPECIAL PRECAUTIONS FOR USE

Not to be administered intravenously (risk of shock).
Injections must be intramuscular and care should be taken to draw back the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.
True allergic responses to TETANUS GAMMA, administered according to the prescribed intramuscular manner are rare.
In the case of shock, treatment should follow the guidelines of shock therapy.
Patients should be kept under observation for at least 20 minutes after administration.

SPECIAL WARNINGS

Pregnancy and lactation

The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials. The product should therefore be administered with caution to pregnant women or breast-feeding mothers. Long lasting clinical experience with immunoglobulin, in particular the application of anti-D immunoglobulin, does indicate that no harmful effects on the course of pregnancy, on the foetus or on the neonate are to be expected.
Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate.

Effects on the ability to drive and use machines

There are no indications that human tetanus immunoglobulin may impair the ability to drive and use machines.

TO BE KEPT OUT OF THE REACH OF CHILDREN

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Live attenuated virus vaccines

The administration of immunoglobulin may impair for a period ranging from at least 6 weeks to 3 months the efficacy of live attenuated virus vaccines such as those against measles, rubella, mumps and varicella.

Interference with serological testing

After injection of immunoglobulin the transitory rise of various passively transferred antibodies into the patient's blood may result in misleading positive results in serological testing.

Incompatibilities

Human tetanus immunoglobulin must not be mixed with other medicinal products.

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TABLE: Recommendation for tetanus wound prophylaxis

Type of wound	Patient not immunised or partially immunised	Patient completely immunised. Time since last booster dose	
		5 to 10 years	> 10 years
Clean-minor	Begin or complete vaccination as per schedule: tetanus toxoid 0.5 ml.	None	Tetanus toxoid 0.5 ml.
Clean-major or tetanus prone	In one arm: human tetanus immunoglobulin 250 I.U.*. In the other arm: tetanus toxoid 0.5 ml *. Complete vaccination as per schedule.	Tetanus toxoid 0.5 ml	In one arm: tetanus toxoid 0.5 ml *. In the other arm: human tetanus immunoglobulin 250 I.U. *.
Tetanus-prone, delayed or incomplete debridement	In one arm: human tetanus immunoglobulin 500 I.U.*. In the other arm: tetanus toxoid 0.5 ml *. Afterwards complete vaccination as per schedule *. Antibiotic therapy.	Tetanus toxoid 0.5 ml Antibiotic therapy.	In one arm: tetanus toxoid 0.5 ml *. In the other arm: human tetanus immunoglobulin 500 I.U. *. Antibiotic therapy.

* Use different syringes, needles and injection sites.
Note: with different preparations of toxoid, the volume of a single booster dose should be modified as indicated on the label.

POSOLOGY

Besides wound cleaning and debridement and human tetanus immunoglobulin injections, active immunisation with tetanus vaccine must be started simultaneously in a separate site of the body (see table).
It is recommended that the physician determines whether a minor wound is "tetanus prone", based on the likelihood that *Clostridium tetani* was present on the object that caused the wound.
Children and adults must receive the same dose.

- Prophylaxis of tetanus.
  250 I.U. for intramuscular use.
  This dosage should be doubled (i.e. 500 I.U.) in case of infractuous or infected wounds, or if the injury occurred more than 24 hours before, or in adults weighing more than the average weight.
- Therapy of clinically manifesting tetanus.
  Several studies suggest the value of human tetanus immunoglobulin in the treatment of clinically manifest tetanus using single doses of 3,000 to 6,000 I.U. in combination with other appropriate clinical procedures.

METHOD OF ADMINISTRATION

Only by intramuscular use.
In case of clotting disorders, where intramuscular injections are contraindicated, human tetanus immunoglobulin may be administered subcutaneously. Careful manual pressure with a compress should be applied on the site after injection.
If large total doses (> 5 ml) are required, it is advisable to administer them in divided doses administered in various sites.

Instructions for use

TETANUS GAMMA pre-filled syringe with solution for injection.
Screw in the plunger shaft and inject.
TETANUS GAMMA solution for injection.
Remove the central protection from the rubber stopper and draw the solution with an injection syringe; change the needle and inject.

Overdose

Consequences of overdose are not known.

UNDESIRABLE EFFECTS

Local pain and tenderness can be observed at the injection site; this can be prevented by dividing larger doses over several injection sites.
Occasionally fever, cutaneous reactions and chills occur.
In rare cases: nausea, vomiting, hypotension, tachycardia, allergic or anaphylactic reactions, including shock, are reported.
When medicinal products prepared from human blood or plasma are administered, infectious diseases due to the transmission of infective agents cannot be totally excluded. This also applies to pathogens of hitherto unknown nature.
To reduce the risk of transmission of infective agents, donors and donations are duly screened. Each unit of plasma used for the production of this hemoderivative was tested and found negative for the presence of HBsAg, HIV_1, HIV_2 and HCV antibodies, and was tested for the ALT content; the plasma pool has also been controlled for the presence of HCV-RNA through a genic amplification technique and the result was non reactive. The production process includes procedures for the removal and inactivation of viruses.
The product is virus inactivated with solvent/detergent method (TNBP/sodium cholate).

Any side effects that have not been described must be communicated to your physician or pharmacist.

Shelf life and stability

The product in its intact package and stored in compliance with the prescribed conditions has the expiry date reported on the label.

WARNING: do not use the product after the expiry date reported on the label.

Special precautions for storage

TETANUS GAMMA solution for injection: store at a temperature between +2 and +8°C, protect from light.
Do not use solutions which are cloudy or have deposits.

DATE OF APPROVAL OF THE PACKAGE INSERT: September 2002.

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