SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tetglob 250 I.U. [Tetanus Immunoglobulin B.P. (Human)]

2. STRENGTH: 250 I.U./Vial.

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of the Component	Specification	Quantity/Vial
Tetanus Immunoglobulin Powder	In-house	250 IU
Sodium Chloride	BP	9.0 mg
Glycine	BP	0.3 M
Thiomersal	BP	0.01%w/v
Water for Injection	USP	q.s.

4. PHARMACEUTICAL FORM

Injection.

5. CLINICAL PARTICULARS

5.1 Therapeutic indications

Tetglob (Tetanus Immunoglobulin B.P.) is indicated for prophylaxis against tetanus following injury in-patients whose immunisation is incomplete or uncertain. Tetglob (Tetanus Immunoglobulin B.P.) should be administered with appropriate wound management. Simultaneous active immunisation must be started using a different injection site and syringe.

Tetglob (Tetanus Immunoglobulin B.P.) is also used therapeutically in the treatment of Tetanus, the recommended dose being 30 to 300 units/kg body weight given intramuscularly into different sites.

Tetglob (Tetanus Immunoglobulin B.P.) obtained from human plasma offers the following important advantages compared with the heterologous serum : experimental indications of better and more prolonged protection; no risk of incidents even after repeated administration; if simultaneous vaccination with

tetanus vaccine is preformed, the formation of specific antibodies is in no way inhibited.

The following table describes when to administer Tetglob (Tetanus Immunoglobulin B.P.) and Tetanus toxoid:

IMMUNE STATUS	**Tetglob** (Tetanus Immunoglobulin B.P.)	**Tetanustoxoid**
Unknown	**Yes**	**Yes**
Incomplete Course of Toxoid	**Yes**	**Yes**
Complete Course of Toxoid:		
Last Booster > 10 years ago	**Yes**	**Yes**
Last Booster 5 - 10 years earlier	**No**	**Yes**
Last Booster within past 5 years.	**No**	**No**

5.2 Route of Administration

Intramuscular.

5.3 Posology and method of administration

Routine prophylaxis dosage schedule:

Adults and children 7 years and older - Tetglob (Tetanus Immunoglobulin B.P.) equivalent to 250 units should be administered by deep intramuscular injection. At the same time, 0.5ml of Tetanus vaccine in a different extremity with a separate syringe and complete immunisation schedule is required to be administered.

Children less than 7 years old - In small children the routine prophylaxis dose of Tetglob (Tetanus Immunoglobulin B.P.) may be calculated by the body weight (4.0 units/kg). However, it may be advisable to administer the entire contents of the vial of Tetglob (Tetanus Immunoglobulin B.P.) (250 units) regardless of child's size, since theoretically the same amount of toxin will be produced in the child's body by the infecting Tetanus organism as it will in an adult's body.

Treatment of active cases of Tetanus - Standard therapy for the treatment of active tetanus including the use of **Tetglob** (Tetanus Immunoglobulin B.P.) must be implemented immediately.

The dosage should be adjusted according to the severity of the infection.

Tetglob (Tetanus Immunoglobulin B.P.) may be administered locally by infiltration into the wound site as well as intramuscularly.

INDICATIONS :	**DOSE**
Prophylaxis : High risk injuries to non-immune and immune patients	250 I.U. in patients 7 years and older (500 I.U. if 24 hours have passed since injury or if there is a risk of heavy contamination)
Treatment : Clinical tetanus	500 IU to 6,000 IU intramuscularly and / or 250 IU - 500 IU intrathecally in adults and children. For T.Neonatorum : 500 to 6,000 IU intramuscularly and / or 250 IU intrathecally.

Mode of Administration:

Tetglob (Tetanus Immunoglobulin B.P.) is given as an intramuscular injection for prophylaxis. Therapeutically Tetglob (Tetanus Immunoglobulin B.P.) can be given intramuscularly or intrathecally.

If large doses (>5ml) are required, it is advisable to administer them in divided doses at different sites.

Before administration of Tetglob (Tetanus Immunoglobulin B.P.) it is recommended to warm the vial to bring it to near body temperature.

Do not use if the product in the vial is turbid.

5.4 Contraindications:

Like any other intramuscular injections Tetglob (Tetanus Immunoglobulin B.P.) is not advocated for patients with bleeding disorders.

In patients with a history of immunoglobulin A (IgA) deficiency or severe anaphylactic reactions to plasma products, the risk-benefit ratio must be considered.

Tetglob (Tetanus Immunoglobulin B.P.) should not be administered intravenously. The safety of intramuscular immunoglobulin in pregnancy has not been established in controlled clinical trials.

5.5 Special warnings and precautions for use:

Tetglob (Tetanus Immunoglobulin B.P.) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations or in patients who are known to have had an allergic response to Thiomersal.

In patients who have severe thrombocytopenia or any coagulation disorder that would contra-indicate intramuscular injection, Tetglob (Tetanus Immunoglobulin B.P.) should be given only if the expected benefits outway the risks.

While administering Tetglob (Tetanus Immunoglobulin B.P.), like administering any other intramuscular injection, care should be taken to drawback the plunger of the syringe before injection in order to be certain that the needle is not in blood vessel.

Tetglob (Tetanus Immunoglobulin B.P.) is preferably administered in the anterolateral aspects of the upper thigh and the deltoid mussel of the upper arm. The gluteal region should not be used routinely because of the risk of injury to the sciatic nerve.

5.6 Interaction with other medicinal products and other forms of interaction

Human Tetanus Immunoglobulin may reduce the immune response to adsorbed tetanus vaccine if the two are administered at the same injection site at the same time. Human Tetanus Immunoglobulin and adsorbed tetanus vaccine should be administered with separate syringes and into different injection sites with separate lymphatic drainage.

Live attenuated virus vaccines

Human Tetanus Immunoglobulin administration may interfere with response to live virus vaccines, such as measles, rubella, mumps and varicella, for a period of at least five weeks and up to three months. Such vaccinations should only be given after an interval of three months after administration of Human Tetanus Immunoglobulin.

Interference with serological testing

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

5.7 Effects on ability to drive and use machines

There are no indications that Human Tetanus Immunoglobulin may impair the ability to drive or use machines.

5.8 Undesirable effects

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitisation to repeated injections of human immunoglobulin is extremely rare.

In the course of routine injections of large numbers of persons with immunoglobulin, there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection.

Local reactions, with pain and tenderness may occur at the injection site. Fever, chills, flushing, lightheadedness, backache, nausea and cutaneous reactions have also been reported.

Persons with selected IgA deficiency may develop antibodies to the small amount of IgA in this preparation, leading to sensitisation and subsequent reaction to IgA-containing material.

After injection of Tetglob (Tetanus Immunoglobulin B.P.) the transitory rise of the various passively transferred antibodies in the patients blood may result in misleading positive results in serological testing.

Administration of vaccines - The effect of live vaccines (e.g. measles, mumps, rubella and varicella) may be inhibited if immunoglobulin containing products (Tetglob) are given. The live vaccines hence are not recommended to be administered until three months after the administration of immunoglobulins.

6. CLINICAL PHARMACOLOGY

Tetglob (Tetanus Immunoglobulin B.P.) provides passive immunity to those individuals who have low or no immunity to the toxin produced by the Tetanus organism, Clostridium tetanus. The antibodies act to neutralise the free form of the powerful exotoxin produced by this bacterium.

Historically, such passive protection was provided by antitoxin derived from equine or bovine serum; however the foreign protein in these heterologous products often produced severe allergic manifestations even in individuals who demonstrated negative skin and or conjunctival tests prior to administration. Estimates of the frequency of these foreign protein reactions following antitoxin of equine origin varied from 5% to 30%.

Passive immunisation with Tetglob (Tetanus Immunoglobulin B.P.) may be undertaken with active immunisation using Tetanus toxoid in those persons who must receive an immediate injection of Tetanus antitoxin and in whom it is desirable to begin the process of active immunisation. The physician may thus supply immediate passive protection against tetanus and at the same time begin formation of active immunisation in the injured individual which upon completion of a full toxoid series will preclude future need for antitoxin. Peak blood levels IgG are obtained approximately two days after intramuscular

injection. The half-life of IgG in the circulation of individuals with normal IgG levels is approximately 23 days.

7. PHARMACEUTICAL PARTICULARS

7.1 List of excipients

1. Sodium Chloride BP
2. Glycine BP
3. Thiomersal BP
4. Water for Injection USP

7.2 Incompatibilities:

Pharmaceutical agents should not normally be added to Human Tetanus Immunoglobulin as their effects on the product have not been established.

7.3 Shelf life:

36 Months.

7.3 Special precautions for storage:

Store at 2^0C - 8^0C. Do not freeze. Protect from light.

Transport in specially designed packs to maintain the product under cool conditions. It is recommended to transport within 72 hours at a temperature not exceeding 37^0C.

7.5 Nature and contents of container:

Tetglob 250 is supplied in a 2 ml USP Type – I tubular glass vial

7.6 Special precautions for disposal and other handling

Human Tetanus Immunoglobulin is for single use only; any used materials and unused solution should be discarded by approved means.

The condition of date expired, or incorrectly stored product cannot be guaranteed. Such product may be unsafe, and should not be used.

Solutions which are cloudy or have deposits should not be used.

8. Manufacturer (name, address, country):
Bharat Serums and Vaccines Limited
Plot No. K-27, Jambivili Village
Anand Nagar
Additional M.I.D.C, Ambernath (East), India.

9. **Owner of the license (name, address, country**)
Bharat Serums and Vaccines Limited.
17th Floor, Hoechst House,
Nariman Point,
Mumbai – 400 021, India.