

FOR THE USE ONLY OF A REGISTERED MEDICAL PRACTITIONER
OR A HOSPITAL OR A LABORATORY

TETANUS IMMUNOGLOBULIN B.P. (HUMAN)

TETGLOB[®]

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DESCRIPTION:

TETGLOB[®] (Tetanus Immunoglobulin B.P.) is a clear to slight opalescent sterile non-pyrogenic solution of hyper immune globulins prepared from the plasma of healthy volunteers specifically immunised against tetanus. Each batch of this product is individually tested and found non-reactive for hepatitis B surface antigen, HIV-1, 2 antibodies and HCV antibodies.

COMPOSITION:

Each vial contains Human Tetanus Immunoglobulin
Equivalent to Tetanus antitoxin.....250 I. U. / 500 I. U. / 1000 I. U.
Stabilizer: Glycine B. P. 0.3 M
Preservative: Thiomersal B. P. 0.01% w/v

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 neutralize 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. Physician may thus supply an 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 deep intramuscular injection. The half life IgG in the circulation of individuals with normal IgG levels is approximately 23 days.

INDICATIONS:

TETGLOB®(Tetanus Immunoglobulin B.P.) is indicated for prophylaxis against tetanus following injury in-patients whose immunisation is complete 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 4 to 300 units/kg body weight given intramuscularly into different sites. (See **DOSAGE & ADMINISTRATION**)

TETGLOB®(Tetanus Immunoglobulin B.P.) obtained from human plasma offers the following important advantages compared with the heterologous serum:

Advantage of TETGLOB®(Tetanus Immunoglobulin B.P.) over **A.T.S.** of animal origin.

Subject	TETGLOB® (Tetanus Immunoglobulin B.P.)	A.T.S.
1. Species	Homologous (Human Donor Plasma)	Heterologous (Animal Origin)
2. Anaphylactic Reaction	None	Possible
3. Protection period	Small	Large
4. Protection Dose	Prophylaxis: 250 I. U. Therapy: 500 – 6,000 I. U.	Prophylaxis: 1500 I. U. Therapy: 10,000 - 25,000 I. U.
5. Repeated dose	23 days	8 days
6. Other advantages	Possible fetal protection as it crosses the placenta	No possible fetal protection

- Experimental indications show better and more prolonged protection;
- No risk of incidents ever after repeated administration;
- If simultaneous vaccination with tetanus vaccine is performed, the formation of specific antibodies is in no way inhibited.

DOSAGE & ADMINISTRATION:

Reference Guidelines for IMMUNISATION STATUS:

The following table describes when to administer **TETGLOB®**(Tetanus Immunoglobulin B.P.) and/or **Tetanus Toxoid** based on the Immunisation status:

IMMUNE STATUS	TETGLOB® (Tetanus Immunoglobulin B.P.)	Tetanus Toxoid
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

Routine prophylaxis dosage schedule:

Adults and Children 7 and older –

TETGLOB®(Tetanus Immunoglobulin B.P.) equivalent to 250 I.U. should be administered by **deep intramuscular** injection. At the same time, 0.5 ml dose of Tetanus vaccine (T. T.) can be given intramuscularly on a different extremity **in a separate syringe** and completion of the immunisation schedule is required with booster doses administered as and when necessary.

Children less than 7 years old –

The dose of TETGLOB®(Tetanus Immunoglobulin B.P.) may be calculated according the body weight in kilograms of the child (4 units/kg) OR 250 I. U. and given as **deep intramuscular** injection.

However, it may be advisable to administer the entire contents of the vials of **TETGLOB®**(Tetanus Immunoglobulin B.P.) 250 I.U. 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 deep intramuscular injection.

Summary of Recommended Dosage Schedule:

INDICATIONS	DOSE
Prophylaxis : <ul style="list-style-type: none">▪ In High risk injuries to non-immune and immune patients (Above 7 Years)▪ In High risk injuries to non-immune and immune patients (Below 7 Years)	250 I.U. Deep IM 500 I.U. Deep IM (if 24 hours have not passed since injury or with a risk of heavy contamination) 4 Units/kg or 250 I.U. Deep IM
Therapeutic : Clinical tetanus <ul style="list-style-type: none">▪ Newborn (Tetanus Neonatorum)▪ Children(Above 7 Years) & Adults	250 I.U. to 500 I.U. IM and/or 250 I.U. intra-theal. 500 to 3,000 I.U. IM and/or 500 I.U. intra-theal.

TETGLOB® (Tetanus Immunoglobulin B.P.) *should not be administered intravenously.*

The safety of **TETGLOB**® (Tetanus Immunoglobulin B.P.) in pregnancy has not been established in controlled clinical trials. Since the safety has not been established by clinical trials it is given to pregnant woman only if clearly indicated.

However as the drug crosses placenta and imparts IgG antibodies therefore the fetus can get protected.

Mode of Administration:

Prophylactic: **TETGLOB**® (Tetanus Immunoglobulin B.P.) is given as deep intramuscular injection for prophylaxis.

Therapeutic: **TETGLOB**® (Tetanus Immunoglobulin B.P.) can be given deep intramuscular or intra-theal.

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

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

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

CONTRAINDICATIONS:

Like any other intramuscular injection **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-benefits ratio must be considered.

PRECAUTIONS & WARNINGS:

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

TETGLOB® (Tetanus Immunoglobulin B.P.) *should not be administered intravenously.*

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 contraindicate intramuscular injection, **TETGLOB**® (Tetanus Immunoglobulin B.P.) should be given only if the expected benefits outweigh 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 antero-lateral aspects of the upper thigh and deltoid muscle of the upper arm. The gluteal region should not be used routinely because of the risk of injury to the sciatic nerve.

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

ADVERSE EFFECTS:

Slight Soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization 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 angio-neurotic 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 reaction have also been reported.

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

After injection of **TETGLOB**®(Tetanus Immunoglobulin B.P.) – A transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.

Teratogenicity: Fetal harm–not known. Teratogenicity not reported

OVERDOSAGE:

Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only manifestations would be pain and tenderness at the local injection site.

STORAGE:

STORE AT 2⁰C – 8⁰C (in a refrigerator). 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 37⁰ C.

PRESENTATION:

Vials containing Human Tetanus Immunoglobulin equivalent to Tetanus antitoxin 250 / 500 / 1000 I.U.

REFERENCES:

New approaches to tetanus prophylaxis. *Lancet* 2 (7461): 449-53, 1966.

Double blind trial of equine antitoxin and human immunoglobulin in tetanus neonatorum. *Lancet* 1 (7710) : 1146-149, 1971.

Specific prophylaxis of tetanus. *JAMA* 171 (4) : 417 – 427, 1959.

Tetanus immunoglobulin. *Martindale – The Extra Pharmacopoeia*, 31st edition, pg. 1646.

Therapeutic trial of intracisternal human tetanus Ig in clinical tetanus. *Trans. Roy. Soc Trop. Med Hyg.* 71:579, 1979.

Therapeutic efficacy of human antitetanus globulin. *Jap. Surg.* 12:26, 1982.

Transplacental immunisation of the human foetus to tetanus by immunisation of the mother *J. Clin. Invest.* 72:987, 1983.



Manufactured in India by:

BHARAT SERUMS AND VACCINES LIMITED

Plot No. K-27, Additional M.I.D.C., Ambarnath (E) - 421 501.