Consumer/Patient Information Leaflet

Brand Name: Tetglob 250 I.U.

(Tetanus Immunoglobulin B.P.) (Human) For Intramuscular / Intrathecal Injection Only

What's in your injectable medicine?

The name of your medicine is Tetglob (Containing Human Tetanus Immunoglobulin as active ingredient). It contains the active ingredient of 250 I.U. in each vial of Tetglob. (Kindly refer to Pack insert for more pharmacological / usage details)

What is Tetanus Immunoglobulin?

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 immunized 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.

How does Tetglob work?

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%.

Your doctor can explain why Tetglob has been given to you.

What is the most important information I should know about Tetglob 250 I.U. (Tetanus Immunoglobulin B.P.) (Human)?

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.

Before using this medication, tells your doctor if:

- you are pregnant, planning to become pregnant or are breast-feeding
- you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- you are allergic to any other medications or substances.

Ask your health care provider if Tetglob may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How should I use Tetglob?

Use **Tetglob** exactly as directed by your doctor.

What happens if I miss a dose?

Contact your doctor if you miss a dose of **Tetglob**.

How shall Tetglob be given to you?

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.

How to store the Medicine?

Store at 2^{0} C - 8^{0} C (in a refrigerator). Do not freeze. Protect from light.

The product license/ authorization holder is:

BHARAT SERUMS AND VACCINES LIMITED

Plot no K-27, Jambivili village, Anand Nagar, Additional M.I.D.C, Ambernath (East) Maharashtra State



Manufactured in India by:

BHARAT SERUMS AND VACCINES LIMITED

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

This is only a summary of the Tetglob 250 IU (Tetanus Immunoglobulin BP) (Human). If you have any questions after reading this leaflet then please ask your doctor who has access to additional information or refer to the pack insert.