Protet-IG™

Human Tetanus Immunoglobulin BP

Presentation
Protet-IG™: Each ml contains Human Tetanus Immunoglobulin BP ≥ 250 IU

Description
Protet-IG is a sterile solution containing human tetanus immunoglobulin which is prepared by Cohn fractionation of plasma of individuals with high titers of antibody to the tetanus antigen and heat inactivation step in manufacturing process (60°C, 10 hrs) is used to inactivate infectious agents such as Hepatitis B virus, Hepatitis C virus, Human immunodeficiency virus and so on.

Indications and uses
Protet-IG is indicated for -

- Prophylaxis of tetanus following injury in patients whose immunization is incomplete or uncertain.
- Therapeutically in the treatment of tetanus.

Tetanus immunoglobulin should always be administered in conjunction with an active tetanus vaccination unless there are contraindications or confirmations of adequate vaccination. The following table describes when to administer human tetanus immunoglobulin and tetanus toxoid:

Immune Status	**Clean minor wounds** (Tetanus infection unlikely)		**All Other Wounds** (Dirty Wounds)	
	Tetanus immunoglobulin	Tetanus toxoid	Tetanus immunoglobulin	Tetanus toxoid
Unknown	No	Yes	Yes	Yes
Incomplete course of toxoid	No	Yes	Yes	Yes
Complete course of toxoid:				
Last booster >10 years ago	No	Yes	Yes	Yes
Last booster 5-10 years earlier	No	Yes	No	Yes
Last booster within past 5 years	No	No	No	No

Dosage and administration
Protet-IG should only be administered by intramuscular injection. Human tetanus immunoglobulin should not be administered by intravenously.

Post-exposure prophylaxis of tetanus
For adults and children single dose of 250 IU should be given. 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 human tetanus immunoglobulin after the exsudative phase of the burn has subsided (about 36 hours after onset of the burn).
At the same time, 0.5ml of tetanus vaccine in a different extremity with a separate syringe and complete immunization schedule is required to be administered.
Therapy of clinically manifest tetanus
For adults and children single doses of 3,000 to 6,000 IU (in combination with other appropriate clinical procedures).

Method of administration

- Human tetanus immunoglobulin should be administered via the intramuscular route
- Do not use solutions which are cloudy or contain residues (deposits/particles)
- Human tetanus immunoglobulin 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
- In the presence of a severe coagulation disorder where intramuscular injections are contraindicated, human tetanus immunoglobulin 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

Contraindications

- Known hypersensitivity to any of the components of the product
- Known hypersensitivity to human immunoglobulins
- Like any other intramuscular injections, human tetanus immunoglobulin 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

Co-administration

- 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 human tetanus immunoglobulin 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.

Use in pregnancy & lactation
The safety for use of human tetanus immunoglobulin in human pregnancy has not been established in controlled clinical trials. Long lasting clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Side effects:
Adverse reaction following administration of human tetanus immunoglobulin is infrequent and mild, but severe local and systemic reactions have occurred rarely.

- Local reactions at the injection site: Local pain, tenderness or swelling.

In rare cases 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.

Precautions:

- Should not be administered intravenously
- A separate sterile syringe must be used for each patient to prevent the possible transmission of hepatitis B and other infectious diseases.
- Should be administered with caution to individuals who have exhibited systemic allergic reactions to immunoglobulin. Epinephrine (0.1~0.5ml, 1:1000) should be available for immediate treatment.
- In patients who have severe thrombocytopenia or any coagulation disorder that would contra-indicated intramuscular injection, human tetanus immunoglobulin should be given only if the expected benefits out way the risks.
- While administering human tetanus immunoglobulin 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.
- Human tetanus immunoglobulin is prepared from human plasma is pasteurized in its bulk condition to reduce the risk of viruses infections but freedom from the risk of unknown viruses (Parvovirus B-19, etc) cannot be assumed. The infused patient is continuously checked for long time after injection.

Overdose
Not applicable.

Storage

- Keep out of the reach and sight of children
- Store at +2 ºC to +8 ºC. Transportation should also be in designed packs to maintain the product temperature +2 ºC to +8 ºC
- Do not freeze. Discard vaccine if frozen
- Protect from light

Commercial pack
Protet-IG™: Each box contains 1 vial of Human Tetanus Immunoglobulin BP and 1 sterile disposable syringe.

Manufactured by
Incepta Vaccine Ltd
Savar, Dhaka, Bangladesh

PRG V.N. 01