PRODUCT MONOGRAPH

TETANUS TOXOID ADSORBED

DIN 01914502

Single dose ampoule (0.5 mL)

For active immunization against tetanus

ID Biomedical Corporation
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Control#: 094858

PMTA01/Version 2.00

▸DESCRIPTION

Tetanus Toxoid Adsorbed as supplied by ID Biomedical Corporation is a sterile, cloudy, uniform suspension of tetanus toxoid, adsorbed on aluminum phosphate, in an isotonic sodium chloride solution.

Each dose (0.5 mL) contains 5 Lf tetanus toxoid, 1.5 mg aluminum phosphate and 0.01% thimerosal as a preservative.

▸INDICATIONS

Tetanus Toxoid Adsorbed is indicated for active immunization against tetanus. It may be used for primary immunization and reinforcing doses against tetanus, as well as in the event of injury for which tetanus prophylaxis is indicated.

▸CONTRA-INDICATIONS

Immunization with Tetanus Toxoid Adsorbed should be postponed in the presence of any acute illness, including febrile illness.

It is contra-indication to administer this vaccine to individuals known to be sensitive to thimerosal.

▸WARNING

If the vaccine is administered to persons receiving immuno suppressive therapy, it should be borne in mind that the expected antigenic response may not be obtained.

▸PRECAUTIONS

Individuals who are hypersensitive to the components of the vaccine may develop allergic reactions. Sterile epinephrine hydrochloride solution 1:1000 should always be readily available in case an acute anaphylactic reaction should occur.

Frequent reinforcing (booster) doses of tetanus toxoid in the presence of adequate or excessive serum levels of tetanus antitoxin have been associated with increased incidence and severity of reactions and should be avoided[4].

▸CAUTION

A separate **sterile** syringe and needle or a **sterile** disposable unit should always be used for each patient to prevent transmission of hepatitis B virus, HIV virus or other infections agent from one person to another.

▸REACTIONS

Mild local reactions such as pain, erythema, tenderness and induration at the injection site are common, and may be associated with systemic reactions including mild to moderate transient fever, chills, malaise and irritability[5 9]. Persistent modules at the injection site have occurred following the use of adsorbed vaccine, but this reaction is unusual[7].

Systemic reactions may develop and take the form of allergic reactions including urticaria and, less commonly, angioneurotic oedema[3 4]. Influenza-like symptoms have been reported and usually occur within 12 hours of vaccination[9]. Neurological complications such as peripheral neuropathies following tetanus toxoid administration have been reported but are rare[2 8].

It has been shown that the incidence of reactions to tetanus toxoid rises according to the number of previously administered doses and occurs mainly in the over-immunized[1, 4.]

▸IMMUNIZATION AND PREGNANCY

When there are clear indications for their use, toxoids may be given to pregnant women. It is preferable, however, to defer immunization until after delivery unless immediate risk is involved[6].

▸DOSAGE

Primary immunization
To establish active immunity against tetanus, it is recommended that 2 doses of **0.5 mL** each of Tetanus Toxoid Adsorbed be administered **intramuscularly** with an interval of 4 weeks between doses. A third dose of **0.5 mL**, which is essential for primary immunization, should be given approximately 6 months to 1 year after the second injection. Active immunization may also be accomplished by the administration of a combined vaccine containing tetanus toxoid.

Reinforcing (booster) doses
For persons who have completed the primary immunization course against tetanus, a single dose of **0.5mL** of Tetanus Toxoid Adsorbed should be administered **intramuscularly** as a reinforcing (booster) dose, at approximately 10 years intervals. A reinforcing dose may also be given with a combined vaccine containing tetanus toxoid.

Procedure at time of injury[6]
No additional dose of tetanus toxoid is recommended, at the time of injury, for those who, within the previous 5 years, have received a complete primary immunization course of injections or a reinforcing dose against tetanus.

If more than 5 years, have elapsed since the completion of a primary course of immunization or receipt of the last reinforcing dose against tetanus, a single dose of Tetanus Toxoid Adsorbed or of an appropriate combined vaccine containing tetanus toxoid should be administered.

Should information about previous administration of tetanus toxoid be inadequate or missing, a prophylactic dose of 250 units of Tetanus Immune Globulin of human origin (TIG) should be administered **in addition to** Tetanus Toxoid Adsorbed in cases of clean minor wounds. If the wounds are severe or grossly contaminated, a dose of 500 units of Human Tetanus Immune Globulin (TIG) is recommended **along with** Tetanus Toxoid Adsorbed.

Should Human Tetanus Immune Globulin (TIG) and Tetanus Toxoid Adsorbed, or a combined vaccine containing tetanus toxoid, be required simultaneously, the two preparations should never be mixed in the same syringe. They should be administered in separate syringes and at different sites.

▸ADMINISTRATION

The skin at the injection site should be cleaned with a suitable antiseptic and dried with a piece of dry sterile cotton. The vaccine should be administered *intramuscularly* into the deltoid muscle or the mid-lateral aspect of the thigh.

Do not inject intravenously or subcutaneously.

In order to avoid intravenous injection, the plunger of the syringe should be pulled back to ensure that no blood is being withdrawn before injecting the desired dose.

▸WITHDRAWAL FROM AN AMPOULE

SHAKE the ampoule to disperse the contents thoroughly **immediately before** withdrawing the dose of vaccine.

Tap the ampoule to ensure that the contents are in the lower portion rather than in the neck of the ampoule.

Using a sterile piece of cotton or a sterile towel, break off the top of the ampoule at the coloured line (no file is required), then using aseptic technique to prevent contamination, and using a **sterile** needle affixed to a **sterile** syringe, withdraw the contents of the ampoule into the syringe, holding the ampoule in such a way that the tip of the needle is kept immersed throughout the withdrawal.

Once the ampoule has been opened, any of its contents not used immediately should be discarded.

▸STORAGE

Tetanus Toxoid Adsorbed should be stored in the refrigerator between 2°C and 8°C.

Do not freeze.

Carefully check the expiry date. An outdated vaccine should never be used.

▸AVAILABILITY

Available in boxes of 5 X 0.5 mL ampoules.

▸NOTIFICATION OF REACTIONS

It is advisable to report any unusual reaction immediately or shortly following any vaccination to the product manufacturer and the provincial epidemiologist.

▸REFERENCES

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4 Edsall, G., et al.: Excessive Use of Tetanus Toxoid Boosters. J.A.M.A. 202(1):17-19, 1967.

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8 Tsairis, P., Dyck, P.J., Mulder, D.W.: Natural History of Brachial Plexus Neuropathy: Report on 99 patients. Arch. Neuro. 27: 109-117, 1972.

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