SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Adsorbed Tetanus Vaccine B.P.

TETANUS TOXOID

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single 0.5 ml human dose contains:

Tetanus Toxoid $\geq$ 5 Lf ($\geq$ 40 IU)

Adsorbed on Aluminium Phosphate, $Al^{+++} \leq 1.25$ mg

Preservative: 0.005% Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The vaccine is used for the prevention of tetanus in infants, children and adults, especially those liable to be exposed to tetanus infection and persons engaged in outdoor activities e.g. gardeners, farm workers and athletes. Tetanus toxoid vaccine is also used in the prevention of neonatal tetanus by immunizing women of childbearing age, and also in the prevention of tetanus following injury.

The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever vaccine, *Haemophilus influenzae* type b, Varicella vaccine and Vitamin A supplementation.

4.2 Posology and method of administration

Posology:

The full basic course of immunization against tetanus toxoid consists of two primary doses of 0.5 ml at least four weeks apart, followed by the third dose 6-12 months later. To maintain a high level of immunity further 0.5 ml booster doses are recommended at every feasible interval (for adults usually 5 to 10 years).

Protection of the newborn against Tetanus:

For prevention of neonatal tetanus, tetanus toxoid is recommended for immunization of women of childbearing age, and especially pregnant women. Tetanus toxoid may be safely administered during pregnancy and should be given to the mother at first contact or as early as possible in pregnancy. A five dose schedule is recommended for previously unimmunized women of childbearing age: after the basic course of immunization with three doses, two additional booster doses should be given, at least one year after the previous dose or during the subsequent pregnancy.

Vaccination of Injured Persons:

For those subjects who have proof of either completing their course of primary immunizations containing tetanus toxoid or receiving a booster shot within the previous 5 years no additional dose of tetanus toxoid is recommended. If more than 5 years have elapsed, and infection with tetanus because of injury or other cause is suspected, 0.5 ml of the adsorbed tetanus toxoid should be given immediately. Where the immunization history is inadequate 1500 IU (3000 old AU) tetanus antiserum and 0.5 ml toxoid should be injected, with separate syringes, to different body sites. (If available, 250 units of tetanus immune globulin (human origin) can be substituted for the tetanus antiserum). A second 0.5 ml dose of toxoid is recommended after 2 weeks and a third dose after a further 1 month. (A note of caution: if horse-origin tetanus antiserum is used in prophylaxis, the patient should be tested for sensitivity to horse serum protein prior to its administration. It is desirable to have 1 ml of Adrenaline solution (1 : 1000) immediately available and the normal precautions followed when injecting antitoxins).

Administration:

Tetanus toxoid should be injected intramuscularly into the deltoid muscle in women and older children. If there are indications for the use of tetanus toxoid in younger children, the preferred site for intramuscular injection is the anterolateral aspect of the upper thigh since it provides the largest muscular mass. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of TT from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided

that all of the following conditions are met (as described in the W.H.O. policy statement: Handling of multi dose vaccine vials after opening, W.H.O./IVB/14.07):

- The vaccine is currently prequalified by W.H.O.
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by W.H.O.;
- The expiry date of the vaccine has not passed.
- The vaccine vial has been, and will continue to be, stored at W.H.O. or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, of one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

4.3 Contraindications

The vaccine should not be given to persons who showed a severe reaction to a previous dose of tetanus toxoid Immunisation should be deferred during the course of any febrile illness or acute infection. A minor febrile illness such as a mild upper respiratory infection should not preclude immunisation.

4.4 Special warnings and precautions for use

Warnings:

The vaccine should not be given to persons who showed a severe reaction to a previous dose of tetanus toxoid.

Precautions:

ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/ kg (0.01 ml/ kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay

in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis.

As with the use of all vaccines, the vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation. There is an increased incidence of local and systemic reactions to booster doses of tetanus toxoid when given to previously immunized persons. Special care should be taken to ensure that the injection does not enter a blood vessel.

IT IS EXTREMELY IMPORTANT WHEN THE PARENT, GUARDIAN, OR ADULT PATIENT RETURNS FOR THE NEXT DOSE IN THE SERIES, THE PARENT, GUARDIAN, OR ADULT PATIENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOMS AND/OR SIGNS OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE.

4.5 Interaction with other medicinal products and other forms of interaction

If passive immunisation for tetanus is needed, TIG (Human) is the product of choice. It provides longer protection than antitoxin of animal origin and causes few adverse reactions. As with other Intramuscular injections, use with caution in-patients on anticoagulant therapy. Immunosuppressive therapies may reduce the immune response to vaccines.

4.6 Pregnancy and lactation

It is recommended that Adsorbed Tetanus Vaccine B.P. can safely be given to pregnant women.

4.7 Effects on the ability to drive and use machines

Adsorbed Tetanus Vaccine B.P. is not reported to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

Reactions are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare. An increased severity of reactions to vaccination may be observed in subjects who have had many booster immunizations.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines

Tetanus toxoid, ATC code J07AM01.

Immunological Data:

Clinical trials performed to assess immunogenicity and reactogenicity of the vaccine and proved that the vaccine is efficacious.

5.2 Pharmacokinetic properties

Pharmacokinetic studies are not required for vaccines.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Aluminium Phosphate (Prepared from Aluminium chloride, Sodium Chloride, Sodium Acetate Trihydrate and Trisodium phosphate Dodecahydrate)

Thiomersal

Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

36 months from the date of manufacture.

6.4 Special precautions for storage

The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. Transportation should also be at 2-8°C. DO NOT FREEZE.

6.5 Nature and contents of container

1 Dose Ampoule	Clear white tubular type I glass ampoule with One Point Cut (OPC) mechanism

6.6 Special precautions for disposal and other handling

Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

SER/IND/011

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 February 2015/ 06 February 2020

10. DATE OF REVISION OF THE TEXT

July 2023