SUMMARY OF PRODUCT CHARACTERISTIC

1. NAME OF THE MEDICAL PRODUCT
TETANUS TOXOID VACCINE ADSORBED

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 0.5 ml contains:
- Tetanus Toxoid \( \geq 5 \text{Lf} \ (\geq 40 \text{IU}) \)
- Aluminium Phosphate \( (\text{AlPO}_4) \) \( \leq 1.5 \text{mg} \)

3. PHARMACEUTICAL FORM
Sterile, opaque suspension

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 child bearing 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 and Yellow Fever Vaccine.

4.2 Posology and method of administration
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 of as early as possible in pregnancy. A five-dose schedule is recommended for 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 Epinephrine Hydrochloride Solution (1 : 1000) immediately available and the normal precautions followed when injection antitoxins).

Method of Inoculation

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.

4.3 Contraindication

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

4.4 Special warnings and precautions for use

- HIV INFECTION

TT vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using these vaccines in symptomatic or asymptomatic HIV infected children.

4.5 Interaction with other medical products and forms of interaction

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4.6 Pregnancy and lactation

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4.7 Effects on the ability to drive and use machines

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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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 0.5 ml contains:
Thiomersal 0.01%

6.2 Incompatibilities

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

Glass ampoule

6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER

MASU CO., LTD.

8. MARKETING AUTHORISATION NUMBER (S)

3/2536

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

31 March 2004

10. DATE OF REVISION OF THE TEXT

22 June 2012