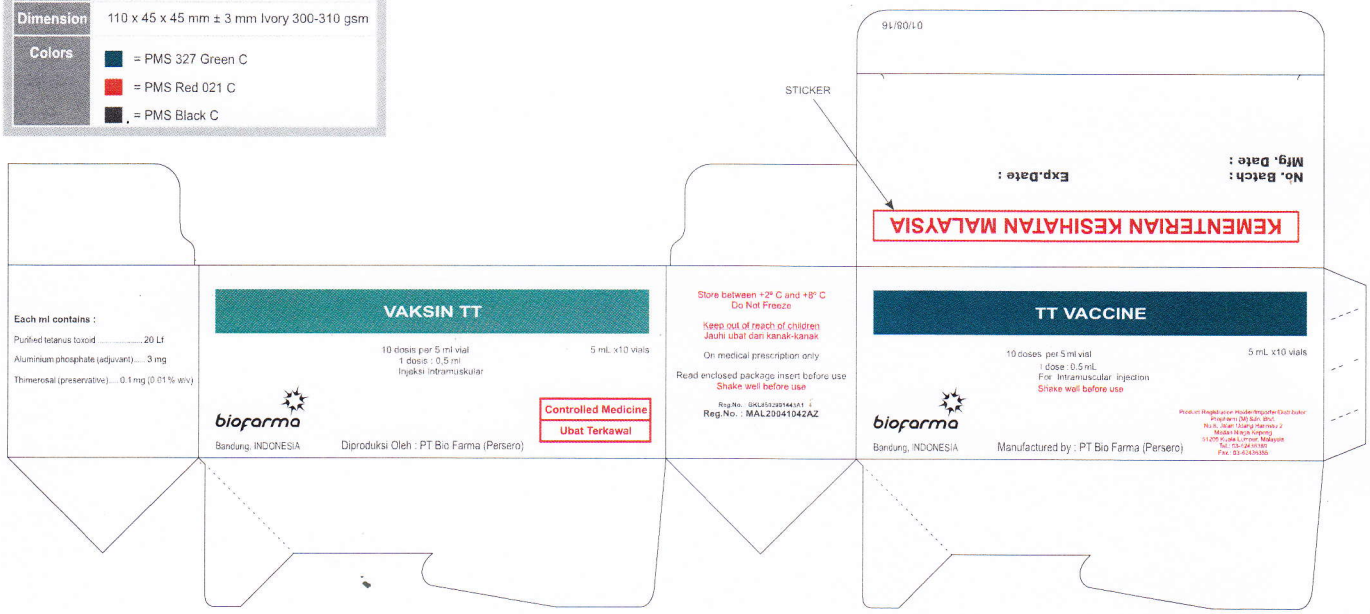
PROPHARM (M) SDN. BHD. (104117-H)
No. 8, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur.
Tel : 03-62436389, 62436396 & 62436348
Fax : 03-62436385
Email : enquiry@propharm.com.my
propharm@gmail.com

Confirmed
11/8/2016

PT. BIO FARMA (PERSERO)	
Product	Box - T T Vaccine(Malaysia)
Edition	01/08/16
Dimension	110 x 45 x 45 mm ± 3 mm Ivory 300-310 gsm
Colors	= PMS 327 Green C = PMS Red 021 C = PMS Black C



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TT VACCINE

(ADSORBED TETANUS VACCINE)
Reg. No.: MAL20041042AZ

DESCRIPTION : A sterile, whitish turbid liquid, free from evident clumps after shaking. The vaccine contains purified tetanus toxoid, adsorbed onto 3mg/ml aluminium phosphate (aluminium content is 0.33mg per dose of 0.5ml). Thimerosal 0.1mg/ml (0.01% w/v) is used as a preservative. One dose of 0.5ml has a potency of at least 40 IU.

COMPOSITION :
1 dose is 0.5ml
One ml contains :-
Purified Tetanus Toxoid (Active Ingredient) -- 20 Lf
Aluminium phosphate(Adjuvant) ---------- 3 mg
Thimerosal (Preservative)---------- 0.1 mg

ACTION AND MODE OF MECHANISMS OF ACTION :
Adsorbed Tetanus Vaccine stimulates active immunity of human body to promote the development of antibodies against tetanus toxin produced by Clostridium tetani.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS)
Not applicable.
TOXICOLOGY (Brief) :
Irreversibility Test and Specific Toxicity Tests were conducted on guinea pigs.
The results showed no sign of tetanus intoxication due to lethal toxin

INDICATIONS :
1) For the prevention of Tetanus
2) Used in the prevention of neonatal tetanus by immunizing women of childbearing age.
3) Immunity booster in cases of injury to vaccinated patients.

CONTRAINDICATIONS :
A severe reaction to previous dose of Tetanus immunization.

SIDE EFFECTS / ADVERSE REACTIONS :
Side effects are rare and mild which include temporary tenderness, pain, swelling, erythema and nodule at injection site. Occasional rashes and fever may occur.

PRECAUTIONS / WARNINGS :
* Shake well before use. A sterile needle and a sterile syringe should be used for each injection.
* Vaccine is injected intramuscularly. Do not administer intravenously.
* It should be given with caution to persons with a history or family history of allergic reactions and those with convulsion.
* Should not be administered to those with febrile illness.
* A solution of 1 in 1,000 adrenaline should be readily available for immediate injection in case of anaphylactic reaction

DRUG INTERACTION : Not reported.
PREGNANCY AND LACTATION :
Tetanus Immunization can be administered safely during pregnancy and lactation even during the First Trimester.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION
Inject intramuscularly. The vaccine vial should be shaken well to homogenize the suspension before use.
Primary immunization: Inject two doses of 0.5ml at an interval of 4 to 8 weeks, followed by the third dose of 0.5ml 6 to12 months later.
Boosters: One 0.5ml injection every 10 years.
To maintain the immunity of women against tetanus through the child-bearing period, from the 6th month of pregnancy onwards, two 0.5ml injections given 2 months apart followed by the 3rd dose one year later. Thereafter, one dose of 0.5ml injection for every subsequent pregnancy and followed by a booster every 10 years.

In the event of injury, an additional reinforcing dose may be given to promote an immediate antibody response, provided such a dose has not been given in the preceding 12 months.
As Vaccination Schemes vary from country to country, the advised schedule for each country must be in accordance with the National Recommendation.

TT can be given safely and effectively at the same time as BCG, Measles, Rubella, Mumps, Polio (OPV and IPV), Hepatitis B, Haemophilus influenzae type b, and Yellow Fever vaccines and Vitamin A supplement.

IMMUNE DEFICIENCY
Individuals infected with human immunodeficiency virus (HIV), whether asymptomatic or symptomatic, should be immunized with TT vaccine according to standard schedules.

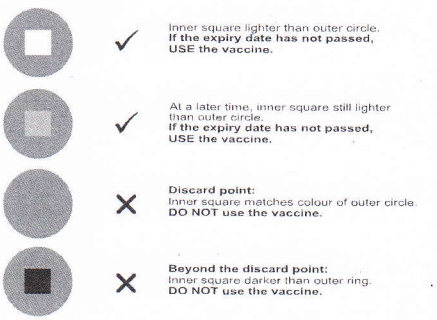
INFORMATION ON USAGE OF MULTI-DOSE VIALS
Once opened, multi-dose vials should be kept between +2°C and +8°C and must not be frozen. **Multi-dose vials from which one or more doses of vaccine have been withdrawn during an immunization session may be used in subsequent immunization session for up to a maximum of 4 weeks,** provided that all of the following conditions are met (as described in the WHO policy statement : The use of opened multi-dose vials in subsequent immunization session. WHO/V&B/00.09):
* The expiry date has not passed ;
* The vaccine is stored under appropriate cold chain conditions ;
* The vaccine vial septum has not been submerged in water ;
* Aseptic technique has been used to withdraw all doses ;
* The vaccine vial monitor (VVM), if attached, has not reached the discard point.
(See figure)

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S) :
Not documented.
PACKING / PACK SIZES :
The vaccine comes in vials of 10 doses and every 10 vials is packed within an inner box which is enclosed with a package insert.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS :
Store at 2 - 8°C. Do not freeze. Protect from light.
Shelf Life : 3 years

FIG. THE VACCINE VIAL MONITOR

The vaccine vial monitor ....



Vaccine Vial Monitor (VVM) is part of the label on TT vaccine. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

Product Registration Holder/Importer/Distributor:
Propharm (M) Sdn. Bhd.
No.8, Jalan Udang Harimau 2
Medan Niaga Kepong
51200 Kuala Lumpur, Malaysia
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Fax.: 03-62436385
e-mail : propharm@gmail.com

NAME AND ADDRESS OF MANUFACTURER :
bioparma
Jl. Pasteur no. 28 - Bandung 40161 - Indonesia
PO Box 1136. Tel. +62 22 2033755. Fax. +62 22 2041306

01/08/15

PT. BIO FARMA (PERSERO)	
Product	Leaflet - T T Vaccine (Malaysia)
Edition	01/08/15
Dimension	120 x 310 mm ± 10 mm HVS 60 gsm
Colors	= PMS 327 Green = PMS Black