Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

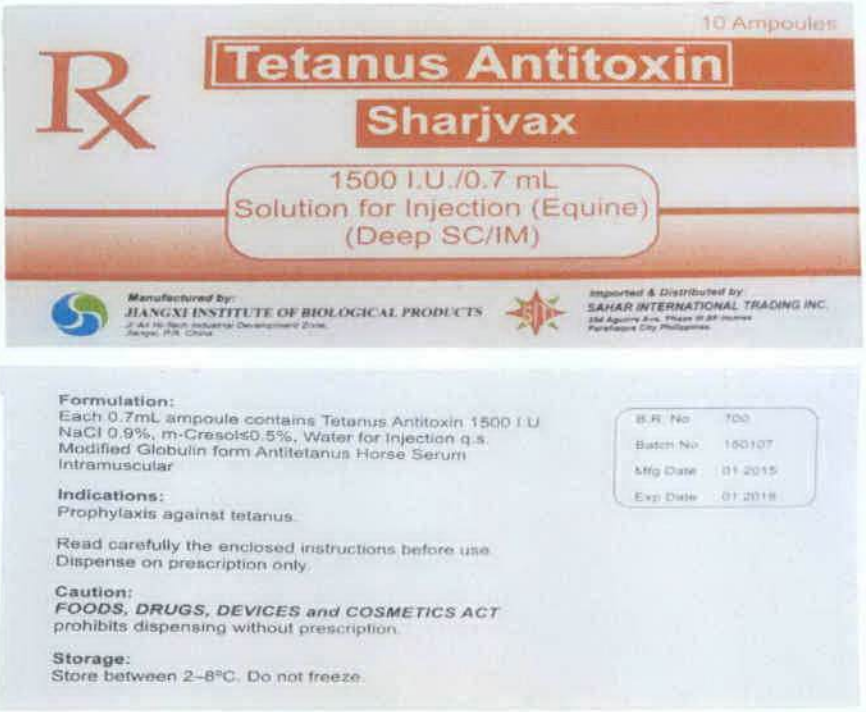
FDA ADVISORY
No. 2016-062-A

20 JUN 2016

PARA: **SA LAHAT NG *HEALTHCARE PROFESSIONALS* AT SA PUBLIKO**

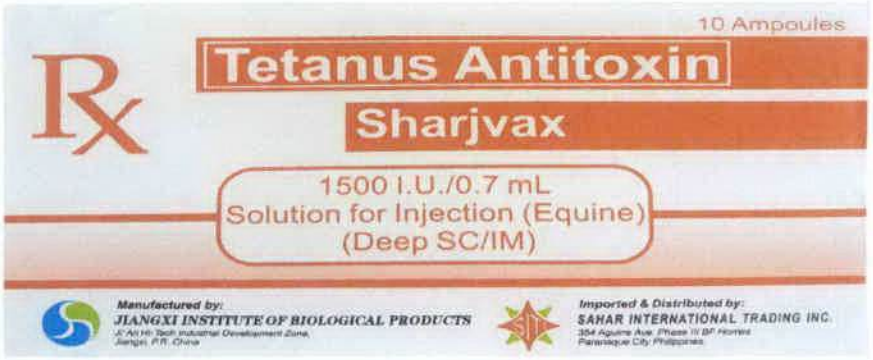
PAKSA: **Babala sa Publiko tungkol sa Paggamit ng Tetanus Antitoxin (Sharjvax) 1500 I.U. / 0.7 mL Solution for Injection at 3000 I.U. / 0 .95 mL Solution for Injection**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa paggamit ng mga pekeng gamot na Tetanus Antitoxin (Sharjvax) 1500 I.U. / 0.7 mL at 3000 I.U. / 0.95 mL Solution for Injection.



Ang *label* ng *ampoules* ay hindi pantay-pantay - indikasyon na ito ay idinikit ng kamay.

Larawan 1. Pekeng Tetanus Antitoxin (Sharjvax) 1500 I.U. / 0.7 mL Solution for Injection (Equine) (Deep SC/IM)



Formulation:
Each 0.7mL ampoule contains Tetanus Antitoxin 1500 I.U.
NaCl 0.9%, m-Cresol≤0.5%, Water for Injection q.s.
Modified Globulin form Antitetanus Horse Serum
Intramuscular

Indications:
Prophylaxis against tetanus.

Read carefully the enclosed instructions before use.
Dispense on prescription only.

Caution:
FOODS, DRUGS, DEVICES and COSMETICS ACT
prohibits dispensing without prescription.

Storage:
Store between 2–8℃. Do not freeze.

B.R. No : 700
Batch No : 150107
Mfg Date : 01.2015
Exp Date : 01.2018

Ang *label* ng *ampoules* ay pantay-pantay - indikasyon na ito ay idinikit ng makina.

Larawan 2. Totoong Tetanus Antitoxin (Sharjvax) 1500 I.U. / 0.7 mL Solution for Injection (Equine) (Deep SC/IM)

HARAP

Ang *dosage strength* na 1500 I.U. / 0.7 mL lamang ang nakalagay sa *package insert*

TETANUS ANTITOXIN

SHARJVAX

Formulation: Solution for Injection (Equine)
Each 0.7mL ampoule contains:
Tetanus Antitoxin . . . . . 1500 IU

Tetanus Antitoxin is prepared from immunized plasma of healthy horses through the process of ammonium sulfate fractionation and ultra filtration after being digested with pepsin. It provides temporary passive immunity against tetanus.

The serum antisera includes antitoxin which are antibodies that combine with and neutralize specific toxins, and antivenin which are antitoxins, directed against toxic of poisonous animals.

Indication and Use:

For those with tetanus symptoms, Tetanus Antitoxin should be given immediately together with surgical and other clinical remedies.
For deep open wounds and those in danger of being infected, prophylactic injection of Tetanus Antitoxin should be given at once. Patients who have had previous injection of Tetanus Toxoid should be given one or more injection of Tetanus Toxoid (but not tetanus antitoxin). To those who have not had previous Tetanus Toxoid injection or without a clear history of immonization, both antitoxins should be given for prophylaxis and permanent immunity.

The right side for subcutaneous injection of the Tetanus Antitoxin is around the deltoid muscle of the upper arm. If Tetanus Toxoid is to be given at the same time separate sites are desirable. The right site for intramuscular injection is the center area of the deltoid muscle or the lateral upper part of the gluteus maximum.

Intravenous route should be used until no untoward reaction occurs after intramuscular or subcutaneous injection. Intravenous injection should be done slowly: not more than 1mL/min and must not exceed 4mL/min afterwards.

The total volume for a single dose should be not more than 40mL for adults and not more than 0.8mL/kg body weight for children. Tetanus Antitoxin may be diluted with dextrose solution or physiological saline for intravenous drip. The drip must be stopped at once if any untoward reaction occurs.

Recommended Dosage:

Prophylactic Use: 1500 I.U. - 3000 I.U.: For adults and children, injection should be repeated after six days when contamination still persists.

For those who have been immunized previously with Tetanus Toxoid, it is advisable to give a booster dose of Tetanus Toxoid only.

Tetanus Antitoxin may be given by Intramuscular (IM) route.

Adverse Effect

1.TYPE 1 hypersensitivity reaction: Anaphylaxis shock may suddenly occur during or after the injection of equine antitoxin with symptoms of glossiness or dysphasia, pale or flush face, chest depression or asthma, cold sweat, nausea or abdominal pain, weak and rapid pulses, hypertension in severe cases.
2. Serum Sickness (Type III hypersensitivity reaction) may occur frequently, 7 to 10 days after the injection. The main symptoms are urticaria, high fever, lymphadenopathy, local swelling and occasionally albuminuidal, vomiting, joint pain as well as erythema, itchiness and edema at the vaccination site.

LIKOD

Contraindication:

- Do not use for patients sensitive to Tetanus Antitoxin.
- Not recommended for pregnant women.

Precaution and Warning:

Before using, the ampoule package must be examined with care. Any broken ampoules containing precipitates or particles must be discarded.

Before injection the antiserum, information should be obtained whenever possible as to whether previous injections of antiserum have been received and whether the patient is subject to hypersensitivity disorders.

Sensitivity testing should be performed before the administration of antisera. The patient must be kept under observation after the administration of doses of antisera. Adrenaline injection a and resuscitation facilities should be available.

Sensitivity test should be done. Dilute the Antitoxin 1:10 with physiological saline (i.e. 0.1 ml antitoxin +0.9 ml of saline) and inject 0.05ml of the diluted antitoxin intracutaneously on the flexor surface of the forearm. A positive reaction characterized by erythema, edema or infiltration appearing in 15-30 minutes denotes sensitivity to horse serum preparation. A negative reaction may be treated in the usual manner, a positive reaction must be desensitized when antitoxin administration is available.

The following desensitization procedure may be recommended: dilute the antitoxin to 1:10 with sterile physiological saline. Inject subcutaneously 0.2ml at first, observe for 30 minutes. If no reaction occurs, give another injection with higher dose, if no reaction occurs, give the third injection, and so forth. If there still no reaction, then the administration of undiluted antitoxin can be started.

Adrenaline should always be at hand. In case of anaphylaxis, adrenaline should be given at once. All patients who developed hypersensitive reactions following injection should be handled properly.

Caution: Foods, Drugs, Devices and Cosmetics Act prohibit dispensing without prescription.

Storage Condition:
Store between 2-8°C. Do not freeze.

Availability:
For Prophylactic use: 1500 IU/ 0.7ML ampoule;

Manufactured by:
JIANGXI INSTITUTE OF BIOLOGICAL PRODUCTS
Ji' An Hi-Tech Industrial Development Zone,
Jiangxi, P.R. China

Imported and Exclusively Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave. Phase III BF Homes
Paranaque City Philippines.

Ang *dosage strength* na 1500 I.U. / 0.7 mL lamang ang nakalagay sa *package insert*

Larawan 4. Package insert ng pekeng Tetanus Antitoxin (Sharjvax) 3000 I.U. / 0.95 mL Solution for Injection (Equine) (I.M.)

HARAP

Lahat ng rehistradong *dosage strength* ay nakalagay sa *package insert*

TETANUS ANTITOXIN

SHARJVAX

Solution for Injection (Equine) I.M.

Each 0.7ml ampoule contains:
Tetanus Antitoxin ..... 1500 IU
Formulation:
Each 0.95ml ampoule contains:
Tetanus Antitoxin ..... 3000 IU
Formulation:
Each 2ml ampoule contains:
Tetanus Antitoxin ..... 5000 IU

[illegible] plasma of healthy horses through the process of ammonium sulfate fractionation and ultra filtration after being digested with pepsin. It provides temporary passive immunity against tetanus.

The term antitoxin includes antitoxin which are antibodies that combine with and neutralize specific toxins, and antivenins which are antitoxins directed against toxic venom of poisonous animals.

Indication and Use:

For those with tetanus symptoms, Tetanus Antitoxin should be given immediately together with surgical and other clinical remedies.

For deep open wounds and those in danger of being infected, prophylactic injection of Tetanus Antitoxin should be given at once. Patients who have had previous injection of Tetanus Toxoid should be given one or more injection of Tetanus Toxoid (but not tetanus antitoxin). To those who have not had previous Tetanus Toxoid injection or without a clear history of immunization, both antitoxins should be given for prophylaxis and permanent immunity.

The right side for subcutaneous injection of the Tetanus Antitoxin is around the deltoid muscle of the upper arm. If Tetanus Toxoid is to be given at the same time, separate sites are desirable. The right site for intramuscular injection is the center area of the deltoid muscle or the lateral upper part of the gluteus maximum.

Intravenous route should be used until no untoward reaction occurs after intramuscular or subcutaneous injection. Intravenous injection should be done slowly: not more than 1ml/min and must not exceed 4ml/min afterwards.

The total volume for a single dose should be not more than 40ml for adults and not more than 0.8ml/kg body weight for children. Tetanus Antitoxin may be diluted with dextrose solution or physiological saline for intravenous drip. The drip must be stopped at once if any untoward reaction occurs.

Recommended Dosage:

Prophylactic Use: 1500 I.U – 5000 I.U.. For adults and children, injection should be repeated after six days when contamination still persists.

For those who have been immunized previously with Tetanus Toxoid, it is advisable to give a booster dose of Tetanus Toxoid only.

Tetanus Antitoxin may be given by Intramuscular (IM) route.

Adverse Effect

1. TYPE I hypersensitivity reaction: Anaphylaxis shock may suddenly occur during or after the injection of equine antitoxin with symptoms of gloominess or dysphoria, pale or flush face, chest depression or asthma, cold sweat, nausea or abdominal pain , weak and rapid pulses, hypertension in severe cases.

2. Serum Sickness (Type III hypersensitivity reaction) may occur frequently, 7 to 10 days after the injection. The main symptoms are urticaria, high fever, lymphadenopathy, local swelling and occasionally albuminuria, vomiting, joint pain as well as erythema, itchiness and edema at the vaccination site.

LIKOD

Contraindication

- Do not use for patients sensitive to Tetanus Antitoxin.

- Not recommended for pregnant women.

Precaution and Warning:

Before using , the ampoule package must be examined with care. Any broken ampoules containing precipitates or particles must be discarded.

Before injecting the antiserum, information should be obtained whenever possible as to whether previous injections of antiserum have been received and whether the patient in subject to hypersensitivity disorders.

Sensitivity testing should be performed before the administration of antisera. The patient must be kept under observation after the administration of doses of antisera. Adrenaline injection and resuscitation facilities should be available.

Sensitivity test should be done. Dilute the Antitoxin 1:10 with physiological saline (i.e. 0.1 ml antitoxin +0.9ml saline) and inject 0.05ml of the diluted antitoxin intracutaneously on the flexor surface of the forearm. A positive reaction characterized by erythema, edema or infiltration appearing in 15-30 minutes denotes sensitivity to horse serum preparation. A negative reaction may be treated in the usual manner, a positive reaction must be desensitized when antitoxin administration is available.

The following desensitization procedure may be recommended: dilute the antitoxin 1:10 with sterile physiological saline. Inject subcutaneously 0.2ml at first, observe for 30 minutes. If no reaction occurs, give another injection with higher dose, if no reaction occurs, give the third injection, and so forth. If there still no reaction, then the administration of undiluted antitoxin can be started.

Adrenaline should always be at hand. In case of anaphylaxis, adrenaline should be given at once. All patients who developed hypersensitive reaction following injection should be handled properly.

Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Storage Condition:

Availability:
For Prophylaxis use: 1500 I.U./0.7ml ampoule;
For Prophylaxis use: 3000 I.U./0.95ml ampoule
For Prophylaxis use: 5000 I.U./2ml ampoule;

Manufactured by:
JIANGXI INSTITUTE OF BIOLOGICAL PRODUCTS

Ji' An Hi-Tech Industrial Development Zone,
Jiangxi, P.R. China

Imported and Exclusively Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave. Phase III BF Homes
Paranaque City Philippines

Lahat ng rehistradong *dosage strength* ay nakalagay sa *package insert*

Larawan 6. Package insert ng totoong Tetanus Antitoxin (Sharjvax) 3000 I.U. / 0.95 mL Solution for Injection (Equine) (I.M.)

Ayon sa pagsusuri ng FDA, ang mga nasabing produkto ay napatunayang peke. Ang Sahar International Trading, Inc., (ang lisensyadong may-ari ng Sharjvax) ay nagsuri din at inihambing ang mga produktong nakolekta sa kanilang mga produkto:

TOTOO AT REHISTRADO *(AUTHENTIC)*	PEKE *(COUNTERFEIT)*
Primary Packaging	
• Ang *label* ng *ampoules* ay pantay-pantay - indikasyon na ito ay idinikit ng makina • Ang *label texts* ay nababasa ng malinaw	• Ang *label* ng *ampoules* ay hindi pantay-pantay - indikasyon na ito ay idinikit ng kamay • Ang *label texts* ay nababasa ngunit malabo, indikasyon na ito ay kinopya lamang mula sa orihinal na *label*
Secondary Packaging	
• *Has a glossy, white background* • *Fair embossed markings*	• *Has yellowish background* • *Embossed markings prominently raised* • Ang kulay ng disensyo ay mas matingkad kaysa sa orihinal
Insert	
• Lahat ng rehistradong *dosage strength* ay nakalagay sa *package insert*	• Ang *dosage strength* na 1500 I.U. / 0.7 mL lamang ang nakalagay sa *package insert*
Physical Appearance of the Content	
• *Clear white in color*	• *Turbid white in color*

Ang mga nasabing produkto ay maaaring magdulot ng panganib sa kalusugan ng mga gagamit ng mga ito, at ang pag-aangkat, at pagbebenta ng mga ito ay paglabag sa *Republic Act No.* 9711 o ang Food and Drug Administration Act of 2009 at *Republic Act No.* 8203 o ang Special Law on Counterfeit Drugs.

Upang mapangalagaan ang kalusugan at kaligtasan ng publiko, ang mga inspektor ng FDA ay inaatasang isagawa ang kanilang mandato ayon sa *Section* 14 ng *Republic Act No.* 9711.

Ang lahat ay binabalaan na ang pagbebenta, pag-aangkat, at pamamahagi ng nasabing mga gamot ay ipinagbabawal at may kaukulang parusa.

Ang lahat ng *Local Government Units* (LGUs) at iba pang mga kaugnay na ahensya ay hinihikayat na siguraduhing ang mga produktong ito ay hindi matatagpuan sa kanilang mga pinamamahalaan.

Pinapaalalahanan ang publiko na bumili lamang ng mga gamot sa mga botika o pamilihang lisensyado ng FDA. Atin pong tandaan na bukod sa pag-iinspek ng mga establisiyamento, ang pagsusuri ng mga produkto, pagrerehistro, at pag-eeksamin sa laboratoryo, ay mga hakbang ng gobyerno upang masiguro ang kaligtasan, kalidad, at bisang mga gamot. Ugaliing hanapin ang *FDA Registration number* sa *label* ng mga produktong binibili. Alalahanin din natin na ang mga *label* ng mga produktong rehistrado sa FDA ay naglalaman ng mga impormasyon sa Ingles o Filipino upang maintindihan ng mga mamimili ang mga nilalaman nito.

Para sa karagdagang impormasyon at mga katanungan, maaaring mag *e-mail* sa info@fda.gov.ph. Hinihikayat ang lahat na sumangguni at magsumbong sa FDA ng anumang patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong produkto sa pamamagitan ng pag *e-mail* sa report@fda.gov.ph o pagtawag sa numero (02)807-8275. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: www.fda.gov/adr-report-new at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

MARIA LOURDES C. SANTIAGO, MSc, MM
OIC, Director General

DTN: 20160517093013