M111698

檔　　號：
保存年限：

天行貿易股份有限公司　通知書

地址：10441 台北市長安東路一段 21 號 2 樓
聯絡電話：(02)2511-0101
傳　　真：(02)2521-3960

親愛的客戶：

本公司代理之「TETANUS IMMUNE GLOBULIN (HUMAN), HYPERTET S/D」，因國內庫存用罄，將改供應同規格之專案輸入藥品「Tetanus Immune Globulin (Human), HyperTET」，如說明，請　查照。

說明：

一、 本公司代理之「TETANUS IMMUNE GLOBULIN (HUMAN), HYPERTET S/D」(健保代碼：KC00461265)，因國內庫存用罄，故依據「必要藥品短缺通報登錄及專案核准製造輸入辦法」申請專案輸入美國同規格品「Tetanus Immune Globulin (Human), HyperTET」(製造廠：美國Grifols Therapeutics LLC)，並已取得衛生福利部同意函 (衛授食字第1110702261號)。

二、 專案輸入藥品「Tetanus Immune Globulin (Human), HyperTET」已進口台灣並取得健保署同意納入健保用藥品項 (健保代碼：X000239265)，其健保支付價自111年11月1日生效，並於112年11月1日停止給付。

三、 使用專案輸入藥品「Tetanus Immune Globulin (Human), HyperTET」時，需知悉以下資訊：

(一). 「Tetanus Immune Globulin (Human), HyperTET」尚未經衛生福利部核准上市，請　貴院所在使用時必須加強該藥品之不良反應監視及通報，若經發現，請立即通知藥物不良反應通報中心，以保障病人權益。

(二). 確保民眾知情同意之權利，藥品使用前應向病人清楚說明與告知，必要時取得病人同意，惟若情況緊急無法取得病患同意時，應註明於病歷，以供查考。

四、 另檢附本公司代理品「TETANUS IMMUNE GLOBULIN (HUMAN), HYPERTET S/D」與專案輸入藥品「Tetanus Immune Globulin (Human), HyperTET」之外包裝對照表。

檔　　號：
保存年限：

附件：一. 專案輸入藥品 HyperTET 之衛生福利部同意輸入函
二. 專案輸入藥品 HyperTET 之外盒照片及英文仿單
三. 專案輸入藥品 HyperTET 之健保藥品代碼及健保支付價核准函
四. 本公司代理品 HYPERTET S/D 與專案輸入藥品 HyperTET 之外包裝對照表

天行貿易股份有限公司
負責人：林德璋

中　華　民　國　111　年　10　月　12　日

附件一

正本

檔　　號：
保存年限：

衛生福利部　函

地址：115204 臺北市南港區忠孝東路六段488號
聯絡人：許寶文
聯絡電話：(02)2787-8237
傳真：(02)2653-2072
電子郵件：xav5611@fda.gov.tw

10442
台北市長安東路一段21號2樓

受文者：天行貿易股份有限公司

裝

發文日期：中華民國111年2月14日
發文字號：衛授食字第1110702261A號
速別：普通件
密等及解密條件或保密期限：
附件：

訂

主旨：貴公司依據「必要藥品短缺通報登錄及專案核准製造輸入辦法」申請專案輸入美國「Tetanus Immune Globulin (Human), HyperTET」(製造廠：美國Grifols Therapeutics LLC)共90支一案，本部同意（簽審文件編號：DHS00001135221，項次：001，單位：SYR），請查照。

說明：

一、復貴公司111年1月26日天藥字第111012601號函。

二、請貴公司通知使用案內藥品之醫療院所以下資訊：

線

(一)經查旨揭藥品尚未經衛生福利部核准上市，請相關醫療院所在使用時必須加強對旨揭藥品之不良反應監視及通報，若經發現，請立即通知藥物不良反應通報中心，以保障病人權益。

(二)確保民眾知情同意之權利，藥品使用前應向病人清楚說明

與告知，必要時取得病人同意，惟若情況緊急無法取得病患同意時，應註明於病歷，以供查考。

三、請貴公司確實管控本案藥品出貨數量及流向，並建立相關統計資料備查。

四、同意旨揭藥品數量之進口有效日期至111年7月31日止。

正本：天行貿易股份有限公司
副本：衛生福利部中央健康保險署、財團法人藥害救濟基金會

部長陳時中

副本

檔　　號：
保存年限：

衛生福利部　函

地址：115204 臺北市南港區忠孝東路六段488號
聯絡人：許寶文
聯絡電話：(02)2787-8237
傳真：(02)2653-2072
電子郵件：xav5611@fda.gov.tw

10442
台北市長安東路一段21號2樓

受文者：天行貿易股份有限公司

發文日期：中華民國111年2月14日
發文字號：衛授食字第1110702261B號
速別：普通件
密等及解密條件或保密期限：
附件：

主旨：本部核准天行貿易股份有限公司至111年7月31日止依據「必要藥品短缺通報登錄及專案核准製造輸入辦法」申請專案輸入美國「Tetanus Immune Globulin (Human), HyperTET」(製造廠：美國Grifols Therapeutics LLC)共90支一案，請貴會轉知所屬會員，詳如本署藥品供應資訊平台(http://dsms.fda.gov.tw/)-專案輸入/製造專區，請查照。

正本：台灣醫學中心協會、中華民國區域醫院協會、中華民國診所協會全國聯合會、中華民國基層醫療協會、台灣社區醫院協會、台灣醫院協會、社團法人臺灣臨床藥學會、中華民國藥師公會全國聯合會、中華民國藥劑生公會全國聯合會
副本：天行貿易股份有限公司

部長陳時中

附件二

colors: Black / PMS 287 / PMS 153 / Unvarnished

K/P Corporation Job No. 42970 / 45648 / 47272
Client: Grifols Therapeutics LLC Cat. No. 3056385
Fonts: Triumvirate, OCR B Edits: reb
Date: 11/13/2019, 11/14, 1/3/2020, 2/4
ID: 1,4,7 Size: 2⅝" x 1⅛" x 6⅛" (9028630 / 08621562 / 06-7722-000) Proof **4**

The patient and physician should discuss the risks and benefits of this product.

For complete dosage and administration information, read enclosed package insert.

For directions for syringe usage, see enclosed package insert.

Do not use if the syringe is prematurely engaged.

Not returnable for credit or exchange.

℞ only

Not made with natural rubber latex.

No preservative

The potency of each syringe is not less than 250 antitoxin units based on the U.S. Standard Antitoxin and the U.S. Control Tetanus Toxin.

Discard unused portion.

Tetanus Immune Globulin (Human)

HyperTET®
250 Units/1 mL

Solution for Intramuscular Injection

Contents: One single-dose disposable syringe with attached needle.

Tetanus Immune Globulin (Human) is a sterile solution of immunoglobulin containing 15%–18% protein stabilized with 0.16 M to 0.26 M glycine.

FOR INTRAMUSCULAR INJECTION ONLY. DO NOT GIVE INTRAVENOUSLY.

Store at 2°C to 8°C (36°F to 46°F). Do not freeze.

1 mL 1 mL 1 mL 1 mL

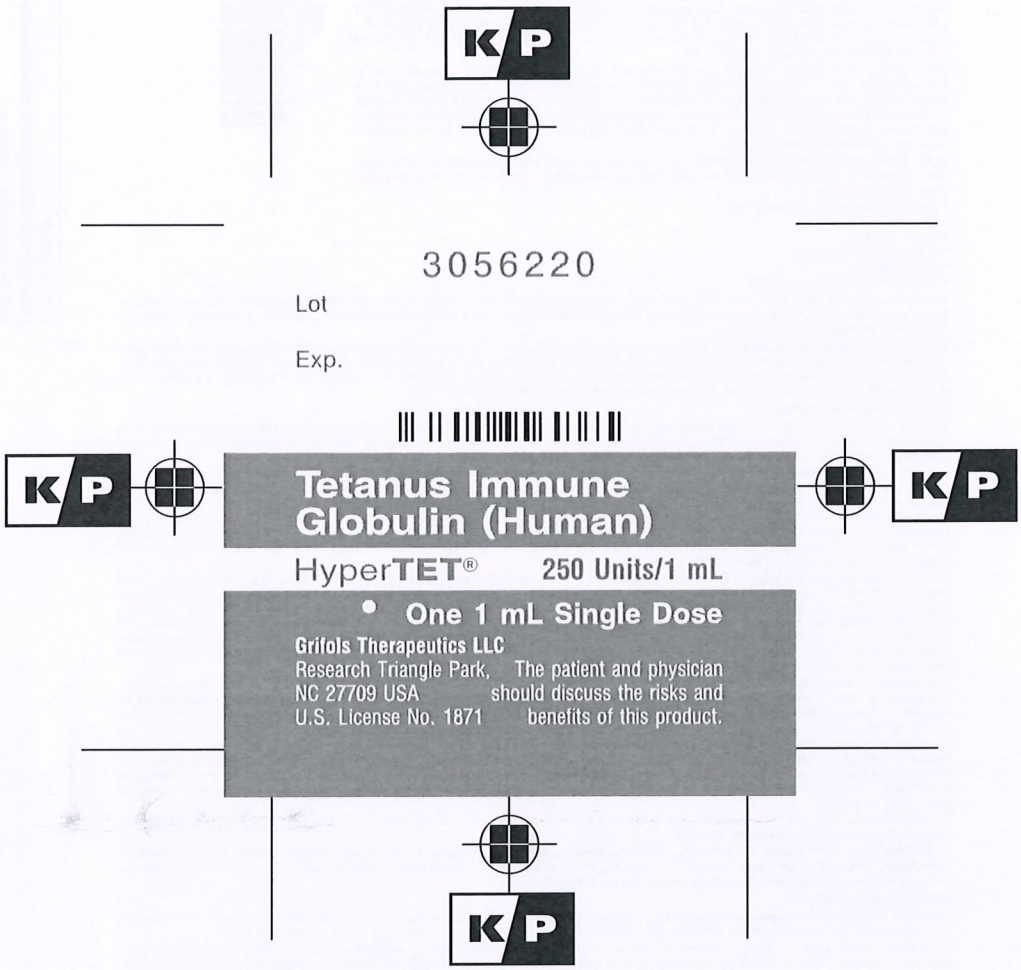
Grifols Therapeutics LLC
Research Triangle Park,
NC 27709 USA
U.S. License No. 1871

NDC 13533-634-02

GRIFOLS

(01)003 13533 634025
Carton: 3056385

06-7722



colors: **Black** / PMS 153

K/P Corporation Job No. 41292 / 47272

Client: Grifols Therapeutics LLC Cat. No. 3056220

Fonts: Triumvirate Edits: reb

Date: 10/29/2019, 10/30, 2/4/2020, 2/5

ID: I2 Size: 1¼" x 1⅜" (Spec 9028574 / 08940579) Proof **4**

Tetanus Immune Globulin (Human)

Hyper**TET**®

250 Units

3059641 (Rev. December 2020)

colors: Black
K/P Corporation Job No. 63015
Client: Grifols Therapeutics LLC Cat. No. 3059641
Fonts: Triumvirate Edits: reb
Date: 12/10/2020, 12/11, 12/16
ID: 1,6,9 Size: 7" x 16" (Spec 9028538 / 08937815) Proof 4

DESCRIPTION

Tetanus Immune Globulin (Human) — Hyper**TET**® is a clear or slightly opalescent, and colorless or pale yellow or light brown sterile solution of human tetanus immune globulin for intramuscular administration. Hyper**TET** contains no preservative. Hyper**TET** is prepared from pools of human plasma collected from healthy donors by a combination of cold ethanol fractionation, caprylate precipitation and filtration, caprylate incubation, anion exchange chromatography, nanofiltration and low pH incubation. Hyper**TET** consists of a 15% to 18% protein solution at a pH of 4.1 to 4.8 in 0.16 M to 0.26 M glycine. The product is standardized against the U.S. Standard Antitoxin and the U.S. Control Tetanus Toxin and contains not less than 250 tetanus antitoxin units per 1 mL.

When medicinal biological products are administered, the risk of infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by epidemiological surveillance of the donor population and selection of individual donors by medical interview; testing of individual donations and plasma pools; and the presence in the manufacturing processes of steps with demonstrated capacity to inactivate/remove pathogen.

In the manufacturing process of Hyper**TET**, there are several steps with the capacity for viral inactivation or removal.(1) The main steps of the manufacturing process that contribute to the virus clearance capacity are as follows:

- Caprylate precipitation/depth filtration
- Caprylate incubation
- Depth filtration
- Column chromatography
- Nanofiltration
- Low pH final container incubation

To provide additional assurance of the pathogen safety of the final product, the capacity of the Hyper**TET** manufacturing process to remove and/or inactivate viruses has been demonstrated by laboratory spiking studies on a scaled down process model using a wide range of viruses with diverse physicochemical properties.

The caprylate/chromatography manufacturing process was also investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered as a model for the variant Creutzfeldt-Jakob disease (vCJD), and Creutzfeldt-Jakob disease (CJD) agents.(1) These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed by the caprylate/chromatography manufacturing process.

CLINICAL PHARMACOLOGY

The occurrence of tetanus in the United States has decreased dramatically from 560 reported cases in 1947, when national reporting began, to a record low of 48 reported cases in 1987.(2) The decline has resulted from widespread use of tetanus toxoid and improved wound management, including use of tetanus prophylaxis in emergency rooms.(3)

Hyper**TET** supplies passive immunity to those individuals who have low or no immunity to the toxin produced by the tetanus organism, *Clostridium tetani*. The antibodies act to neutralize the free form of the powerful exotoxin produced by this bacterium. Historically, such passive protection was provided by antitoxin derived from equine or bovine serum; however, the foreign protein in these heterologous products often produced severe allergic manifestations, even in individuals who demonstrated negative skin and/or conjunctival tests prior to administration. Estimates of the frequency of these foreign protein reactions following antitoxin of equine origin varied from 5%–30%.(4-7) If passive immunization is needed, human tetanus immune globulin (TIG) is the product of choice. It provides protection longer than antitoxin of animal origin and causes few adverse reactions.(3)

Several studies suggest the value of human tetanus antitoxin in the treatment of active tetanus.(8,9) In 1961 and 1962, Nation et al,(8) using Hyper-Tet treated 20 patients with tetanus using single doses of 3,000 to 6,000 antitoxin units in combination with other accepted clinical and nursing procedures. Six patients, all over 45 years of age, died of causes other than tetanus. The authors felt that the mortality rate (30%) compared favorably with their previous experience using equine antitoxin in larger doses and that the results were much better than the 60% national death rate for tetanus reported from 1951 to 1954.(10) Blake et al,(11) however, found in a data analysis of 545 cases of tetanus reported to the Centers for Disease Control from 1965 to 1971 that survival was no better with 8,000 units of TIG than with 500 units; however, an optimal dose could not be determined.

Serologic tests indicate that naturally acquired immunity to tetanus toxin does not occur in the United States. Thus, universal primary vaccination, with subsequent maintenance of adequate antitoxin levels by means of appropriately timed boosters, is necessary to protect persons among all age groups. Tetanus toxoid is a highly effective antigen; a completed primary series generally induces protective levels of serum antitoxin that persist for ≥10 years.(3)

Passive immunization with Hyper**TET** may be undertaken concomitantly with active immunization using tetanus toxoid in those persons who must receive an immediate injection of tetanus antitoxin and in whom it is desirable to begin the process of active immunization. Based on the work of Rubbo,(12) McComb and Dwyer,(13) and Levine et al,(14) the physician may thus supply immediate passive protection against tetanus, and at the same time begin formation of active immunization in the injured individual which upon completion of a **full toxoid series** will preclude future need for antitoxin.

Peak blood levels of IgG are obtained approximately 2 days after intramuscular injection. The half-life of IgG in the circulation of individuals with normal IgG levels is approximately 23 days.(15)

In a clinical study in 12 healthy human adults receiving another hyperimmune immune globulin product, Rabies Immune Globulin (Human), Hyper**RAB**®, prepared by the same manufacturing process, detectable passive antibody titers were observed in the serum of all subjects by 24 hours post injection and persisted through the 21 day study period.

INDICATIONS AND USAGE

Hyper**TET** is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain (see below). It is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus.(8,9,16)

A thorough attempt must be made to determine whether a patient has completed primary vaccination. Patients with unknown or uncertain previous vaccination histories should be considered to have had no previous tetanus toxoid doses. Persons who had military service since 1941 can be considered to have received at least one dose, and although most of them may have completed a primary series of tetanus toxoid, this cannot be assumed for each individual. Patients who have not completed a primary series may require tetanus toxoid and passive immunization at the time of wound cleaning and debridement.(3)

The following table is a summary guide to tetanus prophylaxis in wound management:

Guide to Tetanus Prophylaxis in Wound Management(3)

History of Tetanus Immunization (Doses)	Clean, Minor Wounds		All Other Wounds*	
	Td†	TIG‡	Td	TIG
Uncertain or less than 3	Yes	No	Yes	Yes
3 or more§	No‖	No	No¶	No

* Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns and frostbite.

† Adult type tetanus and diphtheria toxoids. If the patient is less than 7 years old, DT or DTP is preferred to tetanus toxoid alone. For persons ≥7 years of age, Td is preferred to tetanus toxoid alone. (see Dosage and Administration)

‡ Tetanus Immune Globulin (Human).

§ If only three doses of fluid tetanus toxoid have been received, a fourth dose of toxoid, preferably an adsorbed toxoid, should be given.

‖ Yes if more than 10 years since the last dose.

¶ Yes if more than 5 years since the last dose. (More frequent boosters are not needed and can accentuate side effects).

CONTRAINDICATIONS

None known.

WARNINGS

HyperTET** is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob Disease (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics LLC [1-800-520-2807].**

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

Hyper**TET** should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Hyper**TET** should be given only if the expected benefits outweigh the risks.

PRECAUTIONS

General

HyperTET** should not be given intravenously.** Intravenous injection of immunoglobulin intended for intramuscular use can, on occasion, cause a precipitous fall in blood pressure, and a picture not unlike anaphylaxis. Injections should only be made **intramuscularly** and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Intramuscular injections are preferably administered in the deltoid muscle of the upper arm or lateral thigh muscle. The gluteal region should not be used as an injection site because of the risk of injury to the sciatic nerve.(17)

Chemoprophylaxis against tetanus is neither practical nor useful in managing wounds. Wound cleaning, debridement when indicated, and proper immunization are important. The need for tetanus toxoid (active immunization), with or without TIG (passive immunization), depends on both the condition of the wound and the patient's vaccination history. Rarely has tetanus occurred among persons with documentation of having received a primary series of toxoid injections.(3) See table under INDICATIONS AND USAGE.

Skin tests should not be done. The intradermal injection of concentrated IgG solutions often causes a localized area of inflammation which can be misinterpreted as a positive allergic reaction. In actuality, this does not represent an allergy; rather, it is localized tissue irritation. Misinterpretation of the results of such tests can lead the physician to withhold needed human antitoxin from a patient who is not actually allergic to this material. True allergic responses to human IgG given in the prescribed intramuscular manner are rare.

Although systemic reactions to human immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic reactions.

Drug Interactions

Antibodies in immunoglobulin preparations may interfere with the response to live viral vaccines such as measles, mumps, polio, and rubella. Therefore, use of such vaccines should be deferred until approximately 3 months after Tetanus Immune Globulin (Human) — Hyper**TET**® administration.

No interactions with other products are known.

Pregnancy

Animal reproduction studies have not been conducted with Hyper**TET**. It is also not known whether Hyper**TET** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hyper**TET** should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare.

In the course of routine injections of large numbers of persons with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection.

OVERDOSAGE

Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only manifestations would be pain and tenderness at the injection site.

DOSAGE AND ADMINISTRATION

Routine prophylactic dosage schedule:

Adults and children 7 years and older: Hyper**TET**, 250 units should be given by deep intramuscular injection (see PRECAUTIONS). At the same time, but in a different extremity and with a separate syringe, Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use) (Td) should be administered according to the manufacturer's package insert. Adults with uncertain histories of a complete primary vaccination series should receive a primary series using the combined Td toxoid. To ensure continued protection, booster doses of Td should be given every 10 years.(3)

Children less than 7 years old: In small children the routine prophylactic dose of Hyper**TET** may be calculated by the body weight (4.0 units/kg). However, it may be advisable to administer the entire contents of the syringe of Hyper**TET** (250 units) regardless of the child's size, since theoretically the same amount of toxin will be produced in the child's body by the infecting tetanus organism as it will in an adult's body. At the same time but in a different extremity and with a different syringe, Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) or Diphtheria and Tetanus Toxoids Adsorbed (For Pediatric Use) (DT), if pertussis vaccine is contraindicated, should be administered per the manufacturer's package insert.

Note: The single injection of tetanus toxoid only initiates the series for producing active immunity in the recipient. The physician must impress upon the patient the need for further toxoid injections in 1 month and 1 year. Without such, the active immunization series is incomplete. If a contraindication to using tetanus toxoid-containing preparations exists for a person who has not completed a primary series of tetanus toxoid immunization and that person has a wound that is neither clean nor minor, *only* passive immunization should be given using tetanus immune globulin.(3) See table under INDICATIONS AND USAGE.

Available evidence indicates that complete primary vaccination with tetanus toxoid provides long lasting protection ≥10 years for most recipients. Consequently, after complete primary tetanus vaccination, boosters–even for wound management–need be given only every 10 years when wounds are minor and uncontaminated. For other wounds, a booster is appropriate if the patient has not received tetanus toxoid within the preceding 5 years. Persons who have received at least two doses of tetanus toxoid rapidly develop antibodies.(3) The prophylactic dosage schedule for these patients and for those with incomplete or uncertain immunity is shown on the table in INDICATIONS AND USAGE.

Since tetanus is actually a local infection, proper initial wound care is of paramount importance. The use of antitoxin is adjunctive to this procedure. However, in approximately 10% of recent tetanus cases, no wound or other breach in skin or mucous membrane could be implicated.(18)

Treatment of active cases of tetanus:

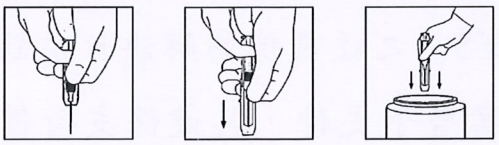
Standard therapy for the treatment of active tetanus including the use of Hyper**TET** must be implemented immediately. The dosage should be adjusted according to the severity of the infection.(8,9)

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. They should not be used if particulate matter and/or discoloration are present.

Hyper**TET** is supplied with a syringe and an attached UltraSafe® Needle Guard for your protection and convenience. Please follow instructions below for proper use of syringe and UltraSafe® Needle Guard.

Directions for Syringe Usage

1. Remove the prefilled syringe from the package. Lift syringe by barrel, **not** by plunger.
2. Twist the plunger rod clockwise until the threads are seated.
3. With the needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles. [Do not remove the needle shield to prepare the product for administration until immediately prior to the anticipated injection time.]
5. Proceed with hypodermic needle puncture.
6. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
7. Inject the medication.
8. Keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated. (See Diagrams A and B)
9. Place entire prefilled glass syringe with guard activated into an approved sharps container for proper disposal. (See Diagram C)



A B C

A number of factors could reduce the efficacy of this product or even result in an ill effect following its use. These include improper storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and biological differences in individual patients. Because of these factors it is important that this product be stored properly and that the directions be followed carefully during use.

HOW SUPPLIED

Hyper**TET** is supplied in 250 unit prefilled disposable syringes with attached needles. Hyper**TET** contains no preservative and is not made with natural rubber latex.

NDC Number	Size
13533-634-02	250 unit syringe

STORAGE

Store at 2–8° C (36–46° F). Solution that has been frozen should not be used. Discard unused portion.

CAUTION

℞ only

U.S. federal law prohibits dispensing without prescription.

REFERENCES

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3. Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures. Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 40 (RR-10): 1-28, 1991.
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5. Scheibel I: The uses and results of active tetanus immunization. *Bull WHO* 13:381-94, 1955.
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3059641

附件三

副本

檔　　號：
保存年限：

衛生福利部中央健康保險署　函

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受文者：天行貿易股份有限公司

發文日期：中華民國111年10月6日
發文字號：健保審字第1110061173號
速別：最速件
密等及解密條件或保密期限：
附件：

天行公文 111.10.07 收文章

主旨：茲通知本保險健保用藥新增品項「Tetanus Immune Globulin(Human),HyperTET」（健保代碼:X000239265），請轉知所屬會員或特約醫事服務機構，請查照。

說明：

一、「Tetanus Immune Globulin(Human),HyperTET」（健保代碼:X000239265）之收載係為解決目前缺藥問題及病人醫療需要，故專案暫予支付，其健保支付價自111年11月1日生效，並於112年11月1日停止給付。

二、旨揭新品項之全民健康保險藥品價格明細表，將於111年10月底置於本署全球資訊網(www.nhi.gov.tw)/健保藥品與特材/健保藥品/健保藥品品項查詢/健保用藥品項/2.健保用藥品項異動檔，可自行下載。

正本：中華民國醫師公會全國聯合會、社團法人中華民國牙醫師公會全國聯合會、中華民國基層醫師協會、中華民國基層醫療協會、中華民國診所協會全國聯合會、中華民國藥師公會全國聯合會、中華民國藥劑生公會全國聯合會、中華民國開發性製藥研究協會、台灣藥品行銷暨管理協會、臺灣製藥工業同業公會、中華民國製藥發展協會、台北市西藥代理商業同業公會、中華民國西藥商業同業公會全國聯

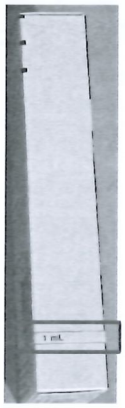
合會、中華民國西藥代理商業同業公會、台灣研發型生技新藥發展協會、社團法人中華民國學名藥協會、台灣醫院協會、台灣私立醫療院所協會、台灣教會醫療院所協會、台北市電腦商業同業公會、本署各分區業務組

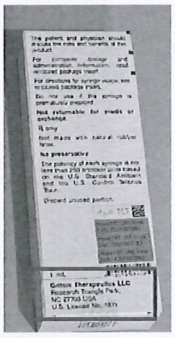
副本：衛生福利部附屬醫療及社會福利機構管理會、衛生福利部社會保險司、天行貿易股份有限公司、衛生福利部食品藥物管理署

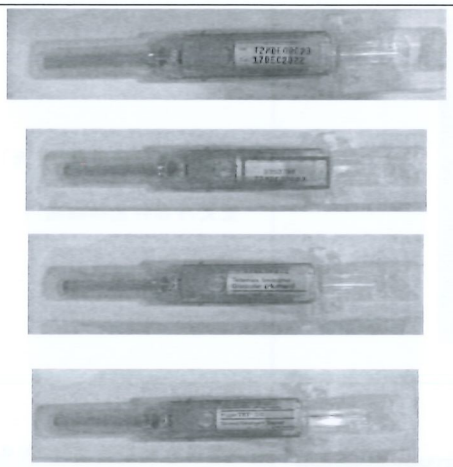
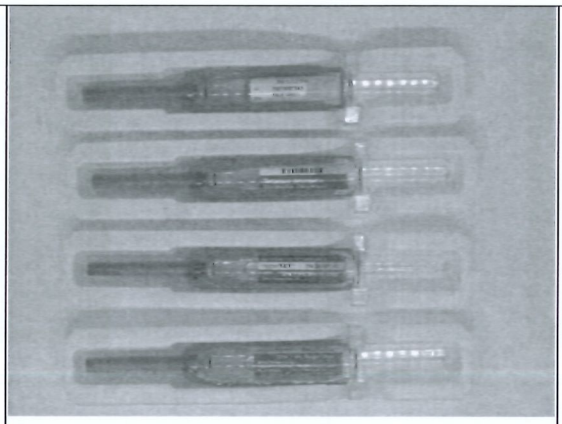
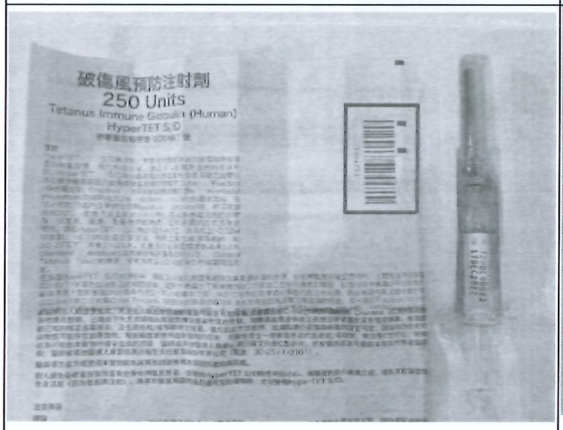
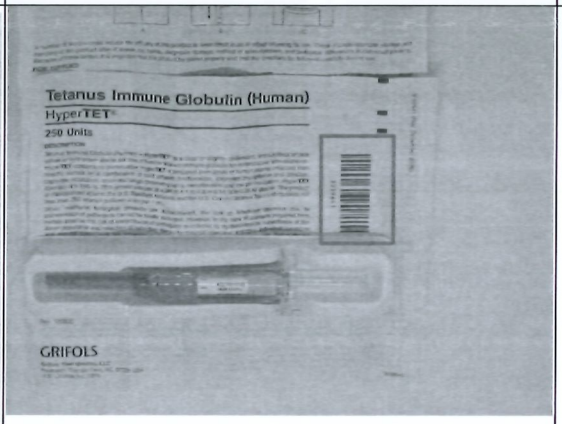
署長 李伯璋

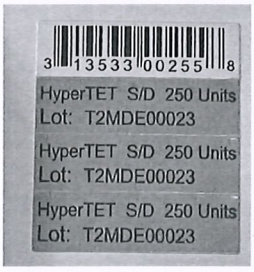
附件四

新舊產品變更比較圖(左舊 右新)

舊包裝 T2MDE00023	新包裝 T02F007283	變更處說明
		產品最小包裝變更處(正面) 變更內容詳見紅框處
		產品最小包裝變更處(側面) 變更內容詳見紅框處

		產品最小包裝變更處(背面) 變更內容詳見紅框處
 		產品最小包裝變更處(頂與底部) 變更內容詳見紅框處 號碼變更： 舊:3054149 新:3056385

		產品標籤號碼變更 變更內容詳見紅框處 舊: 3053758 新: 3056220
		仿單號碼變更： 舊:3054753 新:3059641

		1. 四聯貼變更為五聯貼 2. 新增產品名加上二維條碼 3. 原本一維條碼移至最下方