STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

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Immunization Program

TO: **Health Care Providers**

FROM: **Mick Bolduc**

Vaccine Coordinator-Connecticut Vaccine Program (CVP)

DATE: **December 8, 2016**

SUBJECT: **New Tetanus diphtheria (Td) vaccine, discontinuation of MenHibrix®**

The primary purpose of this communication is to inform providers of a new Td vaccine available from the Connecticut Vaccine Program as well as the discontinuation of MenHibrix® (Meningitis/Hib combination vaccine).

New Td vaccine

Beginning January 1, 2017 the CVP will begin offering a new Tetanus diphtheria (Td) vaccine manufactured by MassBiologics and distributed by Grifols. The vaccine does not have a brand/trade name so it will appear as "Td vaccine" on our revised Vaccine Order Form (VOF). This new Td vaccine can be ordered in quantities as small as 1 dose and the indications and schedule are the same as Sanofi Pasteur's Tenivac® Td vaccine (see attached package insert).

The CVP has also been notified by the CDC that Sanofi's Tenivac® Td vaccine will be temporarily unavailable once existing supplies are depleted at McKesson which is expected to occur within the next 2-3 months. Tenivac® is expected to return to the market in the second half of 2017. Once Tenivac® supplies are exhausted at McKesson, the only Td vaccine available to order will be the new product manufactured by MassBiologics. The CVP will notify providers when that change will take place but **the new Td vaccine can be ordered as of January 1, 2017.**

Discontinuation of MenHibrix® Vaccine

Glaxo SmithKline has notified CDC about a decision to discontinue the manufacture and sale of MenHibrix® [Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine] in the U.S. effective immediately. GSK will stop producing new lots of MenHibrix®

Keeping Connecticut Healthy
DPH
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but will continue to manufacture single Menveo® Meningitis Vaccine and single Hiberix® Haemophilus b vaccine to cover the medical need for high risk patients.

The current CDC inventory of MenHibrix® at McKesson has an expiration date of September 17, 2017. Therefore, if inventory remains, McKesson will continue to ship this vaccine for provider orders until 90 days prior to expiry (June 17, 2017) at which point MenHibrix® will no longer be available to order.

Enclosed is an updated Vaccine Order Form, Vaccine Return Form, and Vaccines Supplied by the CVP.

As always, if you have any questions, please feel free to contact me at (860) 509-7940.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
IMMUNIZATION PROGRAM

Vaccines supplied by the Connecticut Vaccine Program as of January 1, 2017

VACCINE	BRAND NAME	Packaging	NDC #
DTaP	Daptacel	10 pack single dose vials	49281-0286-10
DTaP	Infanrix	10 pack single dose vials	58160-0810-11
DTaP/IPV	Kinrix	10 pack single dose vials	58160-0812-11
DTaP/IPV/Hep B	Pediarix	10 pack single dose syringes	58160-0811-52
DTaP/IPV/Hib	Pentacel	5 pack single dose vials	49281-0510-05
IPV	IPOL	10 dose vial	49281-0860-10
Hepatitis A	Havrix	10 pack single dose vials	58160-0825-11
Hepatitis A	Vaqta	10 pack single dose vials	00006-4831-41
Hepatitis B	Engerix-B	10 pack single dose vials	58160-0820-11
Hepatitis B	Recombivax	10 pack single dose vials	00006-4981-00
Hib	ActHib	5 pack single dose vials	49281-0545-05
Hib	Hiberix	10 pack single dose vials	58160-0818-11
Hib	Pedvax	10 pack single dose vials	00006-4897-00
HPV 9	Gardasil 9	10 pack single dose vials	00006-4119-03
MCV4	Menactra	5 pack single dose vials	49281-0589-05
MCV4	Menveo	5 pack single dose vials	46028-0208-01
Meningococcal Serogroup B	Bexsero	1 single dose syringe	58160-0976-06
Meningococcal Serogroup B	Trumenba	10 single dose syringes	00005-0100-10
Meningococcal Conjugate/Hib	MenHibrix	1 single dose vial	58160-0801-11
MMR	MMR II	10 pack single dose vials	00006-4681-00
MMRV	ProQuad	10 pack single dose vials	00006-4171-00
PCV13	Prevnar 13	10 pack single dose syringes	00005-1971-02
PPSV23	Pneumovax23	10 pack single dose vials	00006-4943-00
Rotavirus	Rotarix	10 pack single dose vials	58160-0854-52
Rotavirus	Rotateq	10 pack single dose tubes	00006-4047-41
Td Vaccine	Td	1 single dose vial	13533-0131-01
Td	Tenivac	1 single dose syringe	49281-0215-15
Tdap	Adacel	10 pack single dose vials	49281-0400-10
Tdap	Boostrix	10 pack single dose vials	58160-0842-11
Varicella	Varivax	10 pack single dose vials	00006-4827-00
Influenza .5mL	Fluarix-Quad	10 pack single dose syringes	58160-0905-52
Influenza .5mL	Flucelvax-Quad	10 pack single dose syringes	70461-0200-01
Influenza .25 mL	Fluzone-Quad	10 pack single dose syringes	49281-0516-25
Influenza .5mL	Fluzone-Quad	10 pack single dose vials	49281-0416-10
Influenza .5mL	Fluzone-Quad	10 pack single dose syringes	49281-0416-50

Revised 12 2 2016

CONNECTICUT VACCINE PROGRAM VACCINE ORDER FORM (VOF)

Clear Form | Save Form

Please read the instructions on page 3 before completing and submitting this form

Completed forms can be FAXED to: **(860) 509-8371** or email to: dph.immunizations@ct.gov

Print Documen

Facility Name and Shipping Address	Date of Report Month / Year Reporting:	Completed by Phone Number	Dates Practice will be closed for the month. Do not include weekends.	PIN

Vaccine Brand	Vaccine	NDC Codes	Pack Size	Doses Ordered	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses Administered
ActHib	Hib	49281-0545-05	5											
Adacel	Tdap	49281-0400-10	10											
Boostrix	Tdap	58160-0842-11	10											
Daptacel	DTaP	49281-0286-10	10											
Engerix-B	Hepatitis B	58160-0820-11	10											
Fluzone-Quad	Influenza .**25** mL Syr.	49281-0516-25	10											
Fluzone-Quad	Influenza .5mL Syr.	49281-0416-50	10											
Fluzone-Quad	Influenza .5mL Vial	49281-0416-10	10											
Fluarix-Quad	Influenza .5mL Syr.	58160-0905-52	10											
Flucelvax-Quad	Influenza .5mL Syr.	70461-0200-01	10											
Gardasil 4	HPV 4	00006-4045-41	10	**N/A**										
Gardasil 9	HPV 9	00006-4119-03	10											
Havrix	Hepatitis A	58160-0825-11	10											
Hiberix	Hib	58160-0818-11	10											
Infanrix	DTaP	58160-0810-11	10											
IPOL	IPV	49281-0860-10	10											
Kinrix	DTaP/IPV	58160-0812-11	10											

Facility Name:_____ **DATE**_____ **PIN** _____

Vaccine Brand	Vaccine	NDC Codes	Pack Size	Doses Ordered	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses On Hand	Lot #	Expiration Date	Doses Administered
MMR II	MMR	00006-4681-00	10											
Menactra	MCV4	49281-0589-05	5											
Menveo	MCV4	46028-0208-01	5											
Pediarix	DTaP/IPV/Hep B	58160-0811-52	10											
Pedvax	Hib	00006-4897-00	10											
Pentacel	DTaP/IPV/Hib	49281-0510-05	5											
Prevnar 13	PCV 13	00005-1971-02	10											
ProQuad	MMRV	00006-4171-00	10											
Recombivax	Hepatitis B	00006-4981-00	10											
Rotarix	Rotavirus	58160-0854-52	10											
Rotateq	Rotavirus	00006-4047-41	10											
Td Vaccine	Td	13533-0131-01	1											
Tenivac	Td	49281-0215-10	1											
Vaqta	Hepatitis A	00006-4831-41	10											
Varivax	Varicella	00006-4827-00	10											
Bexsero	Meningococcal B	58160-0976-06	1											
Trumenba	Meningococcal B	00005-0100-10	10											
****** VACCINES BELOW ARE FOR HIGH RISK PATIENTS ONLY ******														
MenHibrix*	Meningococcal/Hib	58160-0801-11	1											
Pneumovax23*	PPSV23	00006-4943-00	1											

Clear Form | Save Form | Print Document

VACCINE RETURN FORM

Connecticut Vaccine Program

Fax or email completed form to: FAX: 860-509-8371 email: DPH.Immunizations@ct.gov

Please use this form to report all types of state vaccine wastage

1. For vaccines that have spoiled please complete this form and a spoilage letter explaining why the vaccine spoiled and steps you will take to prevent future incidents from occurring. Fax or email the form and letter to the CVP using the contact information above.
2. The form and letter will be reviewed by the VFC Coordinator and a determination will be made if vaccine replacement is required in accordance with the Financial Restitution Policy. Please visit the CVP web page or contact the program at 860-509-7929 for a copy of the policy.
3. After you have submitted this form and spoilage letter to the CVP you will receive a label via email from UPS on behalf of McKesson Specialty Care. If an email is not on file with the CVP you will receive a UPS return label by U.S. mail from McKesson.
4. When you receive the UPS return label, package the vaccine, affix the UPS return label to the package and give to your UPS driver.
5. Return only the vaccine and quantities reported on this return form. N**ever return open multi-dose vials, broken vials or syringes with needles.**
6. If you do not receive a UPS label within 5 days of submitting your return form call the CVP at 860-509-7929.

Revised 12/16 Dept. of Public Health, Immunizations Program, 410 Capitol Avenue; Hartford, CT 06134 Phone (860) 509-7929 Fax (860) 509-8371 www.ct.gov/dph/immunizations

FACILITY NAME	COMPLETED BY	DATE OF REPORT	PIN
	PHONE	SPOILAGE LETTER ATTACHED (Y/N)?	

Vaccine Brand	Vaccine	NDC Code	Lot #	Expiration Date	No. of Doses	Cost Per Dose	Reason For Return
ActHib	Hib	49281-0545-03				**$9.55**	
Adacel	Tdap	49281-0400-10				**$31.37**	
Bexsero	Meningococcal Serogroup B	58160-0976-06				**$98.51**	
Boostrix	Tdap	58160-0842-11				**$31.98**	
Daptacel	DTaP	49281-0286-10				**$16.73**	
Engerix-B	Hepatitis B	58160-0820-11				**$11.60**	
Fluarix-Quad	Influenza .5mL Syringe	58160-0905-52				**$14.43**	
Flucelvax-Quad	Influenza .5mL Syringe	70461-0200-01				**$14.34**	
Fluzone-Quad	Influenza .25 mL Syringe	49281-0516-25				**$19.14**	
Fluzone-Quad	Influenza .5mL Vial	49281-0416-10				**$15.82**	
Fluzone-Quad	Influenza .5mL Syringe	49281-0416-50				**$14.93**	
Gardasil	HPV	00006-4045-41				**$113.54**	
Gardasil 9	HPV 9	00006-4119-03				**$141.60**	
Havrix	Hepatitis A	58160-0825-11				**$17.83**	
Hiberix	Hib	58160-0818-11				**$9.46**	
Infanrix	DTaP	58160-0810-11				**$16.85**	
IPOL	IPV	49281-0860-10				**$12.72**	
Kinrix	DTaP/IPV	58160-0812-11				**$39.57**	
Menactra	MCV4	49281-0589-05				**$89.16**	
MenHibrix	Meningo. Conjugate/Hib	58160-0801-11				**$10.53**	
Menveo	MCV4	46028-0208-01				**$68.32**	
MMR II	MMR	00006-4681-00				**$20.11**	
Pediarix	DTaP/IPV/Hep B	58160-0811-52				**$55.90**	
Pedvax	Hib	00006-4897-00				**$12.48**	
Pentacel	DTaP/IPV/Hib	49281-0510-05				**$56.91**	
Pneumovax23	PPSV23	00006-4943-00				**$46.40**	
Prevnar 13	PCV13	00005-1971-02				**$120.39**	
ProQuad	MMRV	00006-4171-00				**$114.25**	
Recombivax	Hepatitis B	00006-4981-00				**$12.30**	
Rotarix	Rotavirus	58160-0854-52				**$86.75**	
Rotateq	Rotavirus	00006-4047-41				**$66.49**	
Td Vaccine	Td	13533-0131-01				**$13.20**	
Tenivac	Td	49281-0215-10				**$19.69**	
Trumenba	Meningococcal Serogroup B	00005-0100-10				**$95.75**	
Twinrix	Adult Hep A/HepB	58160-0815-52				**$55.35**	
Vaqta	Hepatitis A	00006-4831-41				**$18.23**	
Varivax	Varicella	00006-4827-00				**$88.34**	

NDC 13533-131-00
NDC 13533-131-01

TETANUS AND DIPHTHERIA TOXOIDS ADSORBED

Rx Only

DESCRIPTION

Tetanus and Diphtheria Toxoids Adsorbed (Td) manufactured by MassBiologics is a sterile vaccine for intramuscular injection. After shaking, the vaccine appears as a homogeneous milky white suspension.

Each 0.5 ml dose of MassBiologics' Td is formulated to contain the following active ingredients: 2 Lf of tetanus toxoid and 2 Lf of diphtheria toxoid. Each 0.5 ml dose also contains aluminum adjuvant (not more than 0.53 mg aluminum by assay), < 100 mcg (0.02%) of residual formaldehyde, and a trace amount of thimerosal [mercury derivative, (≤ 0.3 mcg mercury/dose)] (not as a preservative) from the manufacturing process.

The *Corynebacterium diphtheriae* and *Clostridium tetani* organisms are grown on modified Mueller's media[1, 2] which contains bovine extracts. The bovine material used in these extracts is sourced from countries which the United States Department of Agriculture has determined neither have nor present an undue risk for bovine spongiform encephalopathy. Tetanus and diphtheria toxins produced during growth of the cultures are detoxified with formaldehyde. The detoxified materials are then separately purified by ammonium sulfate fractionation. The diphtheria toxoid is further purified by column chromatography. The tetanus and diphtheria toxoids are individually adsorbed onto aluminum phosphate.

The tetanus and diphtheria toxoids induce at least 2 units and 1 unit of antitoxin per ml of serum, respectively, in the guinea pig potency test.

CLINICAL PHARMACOLOGY

TETANUS

Tetanus (also known as lockjaw) is a serious, often fatal disease caused by an extremely potent neurotoxin produced by *C. tetani*.

Protection against disease is due to the development of neutralizing antibodies to tetanus toxin. A serum tetanus antitoxin level of 0.01 IU/ml measured via a neutralization assay is considered the minimum protective level.[3, 4] The efficacy against tetanus of MassBiologics' Td is supported by the following:

1. Response to primary series. Of 20 adults with less than 0.0025 units/ml of tetanus antitoxin in preimmunization serum, 14 (70%) had antitoxin concentrations of 0.01 or greater after 2 doses of Td (2 Lf tetanus toxoid dose). After 3 doses of Td, 16 of 16 adults achieved 0.01 antitoxin units/ml.

2. Response to booster doses. Booster doses of Td at doses of 1 Lf and 5 Lf of tetanus toxoid induced tetanus antitoxin levels greater than 0.01 units/ml when administered to all 36 adults who had received prior tetanus immunizations.[5]

DIPHTHERIA

Diphtheria is an acute toxin-mediated disease caused by toxigenic strains of *C. diphtheriae*. Protection against disease is due to the development of neutralizing antibodies to diphtheria toxin. A serum diphtheria antitoxin level of 0.01 IU/ml is the lowest level giving some degree of protection.[3, 6] The efficacy against diphtheria of MassBiologics' Td is supported by the following:

1. Response to primary series. Of 10 adults with less than 0.001 units/ml of diphtheria antitoxin in preimmunization serum, 50% had antitoxin concentrations of 0.01 or greater after 2 doses of Td (2 Lf diphtheria toxoid dose). After 3 doses of Td, 6 of 6 adults achieved 0.01 antitoxin units/ml.

2. Response to booster doses. In clinical trials, booster doses of Td formulated to contain 1 Lf and 5 Lf of diphtheria toxoid, both induced antitoxin levels greater than 0.01 units/ml when administered to adults with prior diphtheria immunity. [5, 7, 8] In 140 adolescent males given a single booster dose of the 1 Lf formulation, all achieved an antitoxin titer of 0.01 units/ml or higher.[8]

INDICATIONS AND USAGE

MassBiologics' Td is a vaccine indicated for active immunization for the prevention of tetanus and diphtheria. This vaccine is approved for use in persons 7 years of age and older.

CONTRAINDICATIONS

A severe allergic reaction (e.g., anaphylaxis) occurring after a previous dose of this vaccine, or any other tetanus or diphtheria toxoid-containing vaccine, or any component of this vaccine is a contraindication to administration of MassBiologics' Td vaccine. (See **DESCRIPTION**). Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with diphtheria or tetanus components should be carried out. Alternatively, such individuals may be referred to an allergist for evaluation if further immunizations are to be considered.

WARNINGS

FREQUENCY OF ADMINISTRATION

More frequent administration of MassBiologics' Td than described in **DOSAGE AND ADMINISTRATION** may be associated with an increased incidence and severity of adverse reactions.

ARTHUS REACTIONS

Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of a tetanus toxoid-containing vaccine usually have high serum tetanus antitoxin levels and should not receive MassBiologics' Td more frequently than every 10 years, even for tetanus prophylaxis as part of wound management. (See **DOSAGE AND ADMINISTRATION**).

GUILLAIN-BARRÉ SYNDROME

A review by the Institute of Medicine found evidence for a causal relation between tetanus toxoid and Guillain-Barré Syndrome.[9] If Guillain-Barré Syndrome occurred within 6 weeks after receipt of a previous dose of tetanus toxoid-containing vaccine, the decision to give subsequent doses of MassBiologics' Td or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. [10]

Vaccination with MassBiologics' Td may not protect all individuals.

PRECAUTIONS

GENERAL

Epinephrine injection (1:1000) and other appropriate agents and equipment must be immediately available should an acute anaphylactic reaction occur.

Prior to the administration of MassBiologics' Td, the vaccine recipient's current health status and health history should be reviewed. This includes a review of the immunization history of the patient, the presence of any contraindications to immunization, and any adverse events after previous immunizations to allow an assessment of the benefits and risks of vaccination. (See **CONTRAINDICATIONS** and **WARNINGS**).

If MassBiologics' Td is administered to immunocompromised persons (whether from disease or treatment) the expected immune response may not be obtained.

INFORMATION FOR PATIENTS

Prior to administration of MassBiologics' Td, patients, parents or guardians should be informed by the health care provider of the benefits and risks of immunization with Td and of the importance of completing the primary immunization series or receiving recommended booster doses.

The health care provider should inform the patient, parent, or guardian of the potential for adverse reactions that have been temporally associated with MassBiologics' Td or other vaccines containing similar ingredients. Patients, parents or guardians should be instructed to report any suspected adverse reactions to their health care provider.

According to the National Childhood Vaccine Injury Act of 1986, Vaccine Information Statements must be provided by the health care provider with each vaccine dose administered.[10]

DRUG INTERACTIONS

Patients who are on immunosuppressive therapy, including alkylating agents, antimetabolites, cytotoxic drugs, irradiation, or corticosteroids (used in greater than physiologic doses), may have a reduced immune response to vaccines.

No safety and immunogenicity data are available on the concomitant administration of MassBiologics' Td vaccine with other U.S. licensed vaccines.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

No studies have been performed with MassBiologics' Td to evaluate carcinogenicity, mutagenic potential, or impairment of fertility.

PREGNANCY CATEGORY C

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

NURSING MOTHERS

It is not known whether MassBiologics' Td is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when MassBiologics' Td is administered to a nursing woman.

PEDIATRIC USE

MassBiologics' Td is not approved for use in infants and children younger than 7 years of age. The safety and effectiveness of MassBiologics' Td in this age group have not been established.

GERIATRIC USE

No studies have been performed with MassBiologics' Td in adults aged 65 years and older in order to determine whether they respond differently than younger subjects.

ADVERSE REACTIONS

DATA FROM CLINICAL TRIALS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. However, the adverse reaction information from clinical trials provides a basis for identifying adverse events that appear to be related to vaccine use and for approximating rates. Data on adverse reactions following fluid and adsorbed preparations of MassBiologics' Td with various doses of the diphtheria and tetanus components have been reported in a series of studies.[5, 7, 8, 11, 12]

POSTMARKETING REPORTS

The following adverse events have been identified during post-approval use of MassBiologics' Td. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to vaccination. The following adverse events were included because of seriousness or frequency of reporting:

General Disorders and Administration Site Conditions: Injection site reactions, including pain, tenderness, erythema, induration, pruritis, swelling and warmth; peripheral oedema, pyrexia, malaise

Nervous System Disorders: Dizziness, headache, convulsions

Musculoskeletal and Connective Tissue Disorders: Myalgia, musculoskeletal stiffness or pain, arthralgia

Skin and Subcutaneous Tissue Disorders: Rash

Gastrointestinal Disorders: Nausea

Infections and Infestations: Cellulitis

REPORTING OF SUSPECTED ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact MassBiologics at 1-800-457-4626 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

DOSAGE AND ADMINISTRATION

PRIMARY IMMUNIZATION

MassBiologics' Td may be used in persons 7 years of age and older who have not been previously immunized against tetanus and diphtheria, as a primary immunization series consisting of three 0.5 ml doses. The first two doses are administered 4-8 weeks apart and the third dose is administered 6-12 months after the second dose.

MassBiologics' Td may be used to complete the primary immunization series for tetanus and diphtheria, following one or two doses of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (whole-cell DTP), Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and/or Diphtheria and Tetanus Toxoids Adsorbed (DT) vaccine. However, the safety and efficacy of MassBiologics' Td in such regimens have not been evaluated.

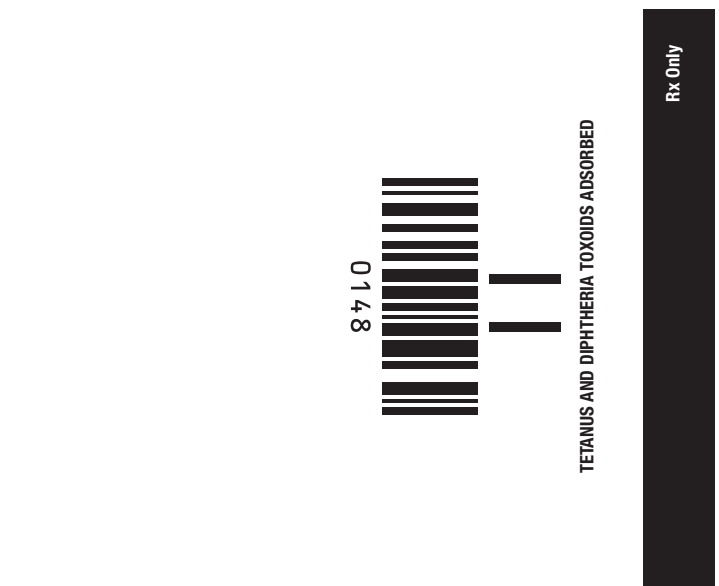
ROUTINE BOOSTER IMMUNIZATION

MassBiologics' Td may be used for routine booster immunization against tetanus and diphtheria in persons 7 years of age and older who have completed primary immunization against tetanus and diphtheria. Routine booster immunization against tetanus and diphtheria is recommended in children 11-12 years of age and every 10 years thereafter.[10]

The Advisory Committee on Immunization Practices (ACIP) has specific recommendations on booster immunization against tetanus and diphtheria for adolescents and adults.[10, 13, 14]

TETANUS PROPHYLAXIS IN WOUND MANAGEMENT

For active tetanus immunization in wound management of patients 7 years of age and older, a preparation containing tetanus and diphtheria toxoids is preferred instead of single-antigen tetanus toxoid to enhance diphtheria protection.[15] MassBiologics' Td is approved for wound management of patients 7 years of age and older.



The need for active immunization with a tetanus toxoid-containing preparation, with or without Tetanus Immune Globulin (TIG) (Human) depends on both the condition of the wound and the patient's vaccination history (Table 1).

When indicated, TIG (Human) should be administered using a separate needle and syringe at a different anatomic site, according to the manufacturer's package insert. If a contraindication to using a tetanus toxoid-containing vaccine exists in a person who has not completed tetanus primary immunization and other than a clean, minor wound is sustained, only passive immunization with TIG (Human) should be given.[15]

TABLE 1 GUIDE TO TETANUS PROPHYLAXIS IN ROUTINE WOUND MANAGEMENT IN PERSONS AGED 7 YEARS AND OLDER[13, 14, 15]

History of Adsorbed Tetanus Toxoid (Doses)	Clean, Minor Wounds		All Other Wounds*	
	Td†	TIG	Td†	TIG
Unknown or < 3	Yes	No	Yes	Yes
≥ 3 ‡	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.

† The ACIP has specific recommendations on use of Td or Tetanus Toxoid, Reduced Diphtheria Toxoids and Acellular Pertussis Vaccine Adsorbed (Tdap) in adolescents and adults.[13, 14]

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

§ Yes, if ≥ 10 years since the last tetanus toxoid-containing vaccine dose.

¶ Yes, if ≥ 5 years since the last tetanus toxoid-containing vaccine dose. (More frequent boosters are not needed and can accentuate side effects.)

DIPHTHERIA PROPHYLAXIS FOR CASE CONTACTS

MassBiologics' Td may be used for post-exposure diphtheria prophylaxis in persons 7 years of age and older who have not completed primary vaccination, whose vaccination status is unknown, or who have not been vaccinated with diphtheria toxoid within the previous 5 years. Consult ACIP recommendations for additional interventions for post-exposure diphtheria prophylaxis.[15]

ADMINISTRATION

Shake the vial well to resuspend the vaccine before withdrawing the dose. After shaking, MassBiologics' Td is a homogenous milky white suspension. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If these conditions exist, MassBiologics' Td should not be administered.

Inject 0.5 ml of MassBiologics' Td intramuscularly. The preferred site is the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.

Do not administer this vaccine intravenously, subcutaneously, or intradermally.

MassBiologics' Td should not be combined through reconstitution or mixed with any other vaccine.

HOW SUPPLIED

The stopper of the vial is latex free.
MassBiologics' Td is supplied in a package of 10 single dose vials.
NDC No. 13533-131-00 is the code for individual single dose (0.5ml) vials.
NDC No. 13533-131-01 is the code for the package containing ten vials.

STORAGE

Store at 2°C - 8°C (36°F - 46°F). DO NOT FREEZE. Discard product if exposed to freezing.

Do not use vaccine after expiration date.

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