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 0.5 mg aluminum hydroxide) and a trace amount of thimerosal (mercury derivative, ≤ 0.3 mcg mercury/dose) (not as a preservative) from the manufacturing process.

The Coronavirus disease and COVID-19 vaccine organisms are grown on modified Mueller's medium which contains bovine extract. The bovine material used in these extracts is sourced from countries where the United States Department of Agriculture has determined neither tea nor coffee is grown.

Protection against disease is due to the development of neutralizing antibodies to tetanus toxoid and to diphtheria toxoid given intramuscularly. Administration of tetanus toxoid induces antibody levels greater than 0.01 units/ml when administered to all eligible adults who have received prior tetanus immunizations.

DIPHTHERIA
Diphtheria is an acute toxin-mediated disease caused by toxinogenic strains of C. diphtheriae. Protection against diphtheria is achieved by the development of neutralizing antibodies to diphtheria toxoid. A serum diphtheria antitoxin level of 0.1 IU/ml is the lowest level giving some degree of protection.

INDICATIONS AND USAGE
MassBiologics’ Td is a mucosal 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.

ARTHYRIE REACTIONS
Persons who experienced an Altus-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 Medical and Public Health in the Netherlands has found evidence for a causal relation between tetanus toxoid and Guillain-Barré Syndrome. If Guillain-Barré Syndrome occurs 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 risks of such vaccination. (See CONTRAINDICATIONS and DOSAGE AND ADMINISTRATION.)

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 Injury Statements must be provided by the health care provider with each vaccine dose administered.

DRUG INTERACTIONS
None known.

ADVERSE REACTIONS
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. Adverse reactions occurring with the concurrent Administration of concomitant vaccines are discussed in the Warnings section of the product label.

ADVERSE REACTIONS FOLLOWING IMMUNIZATION WITH TETANUS AND DIPHTHERIA TOXOIDS ADSORBED
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:

Allergic reactions

Contraindications

Adverse events following immunization with tetanus and diphtheria toxoids

Asthma

Neuromuscular and neurologic disorders

Musculoskeletal system and connective tissue disorders

Nervous system disorders

Injection site reactions, including pain, tenderness, reaction to physical manipulation, and hematoma formation

Postmarketing reports

GI disorders

Hypersensitivity

Skin and Subcutaneous tissue disorders

Miscellaneous

Antibiotics and antifungal agents

Injection site reactions, including pain, tenderness, reaction to physical manipulation, and hematoma formation

Postmarketing reports

Respiratory, thoracic, and mediastinal disorders

Sinusitis

Subcutaneous tissue disorders

Severe allergic reaction including anaphylaxis

Other

Respiratory, thoracic, and mediastinal disorders

Sinusitis

Subcutaneous tissue disorders

Severe allergic reaction including anaphylaxis
The need for active immunization with a tetanus toxoid-containing preparation, with or without Tdap, depends on both the condition of the wound and the patient’s vaccination history (Table 1).

When indicated, Td (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 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. 8

### TABLE 1: GUIDANCE FOR ROUTINE WOUND MANAGEMENT IN PERSONS AGED 7 YEARS AND OLDER

<table>
<thead>
<tr>
<th>History of Ancestral Tetanus</th>
<th>Toxoid (Dosage)</th>
<th>DIPHTHERIA PROPHYLAXIS FOR CASE CONTACTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated</td>
<td>Td</td>
<td>TIG</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5 years since last tetanus toxoid-containing vaccine dose.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>≥ 10 years since last tetanus toxoid-containing vaccine dose.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### ADMINISTRATION

Shake the vial well to resuspend the vaccine before withdrawing the dose. After shaking, MassBiologics’ Td is a homogenous, white, beta-lactamase stable 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. 13533-131-01 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.

**REFERENCES**