TDVAX™ manufactured by MassBiologics is a sterile vaccine for intramuscular injection. After shaking, the vaccine appears as a clear, colorless to pale yellow, viscous solution.

Each 0.5 mL dose of MassBiologics’ TDVAX is formulated to contain the following active ingredients: 2.0 mg of tetanus toxoid and 1.0 mg of diphtheria toxoid in 1.0 mL of isotonic buffer, in addition to the excipients listed below (not more than 0.3 mg as polysorbate 80 by mass), ≤100 ppm (0.02%) of residual formaldehyde, and a trace amount of sodium citrate, sodium dihydrogen phosphate, and monosodium phosphate to provide buffering capacity.

The Connaught diphtheria and Chiron tetanus toxoids are grown on neomycin-resistant Mu50 cells, which contain bacterial-derived neomycin resistance. The bovine material and those in this vaccine are 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 the fermentation process are detoxified and purified by aqueous acetone fractionation. The toxoid is further purified by cation chromatography. The tetanus and diphtheria toxoids contain very low levels of endotoxin.

The tetanus and diphtheria toxoids to be used in 2 doses at 1 year of age and 1 year thereafter.

MassBiologics’ TDVAX was approved for licensure on July 31, 2003.

In response to primary series. Of 10 adults with less than 0.001 units/mL of diphtheria antitoxin in pre-

The health care provider should inform the patient, parent, or guardian of the potential for adverse reactions.

Due to the nature of the study, children who received the vaccine were not observed for at least 30 days after vaccination, and for 60 days in the group in which children were observed for at least 30 days.

Prior to the administration of MassBiologics’ TDVAX, the vaccine recipient’s current health status and available should an acute anaphylactic reaction occur.

FREQUENCY OF ADMINISTRATION

CONTRAINDICATIONS

In response to primary series. Of 10 adults with less than 0.0025 units/mL of tetanus antitoxin in pre-

Rates of adverse reactions from each component of the vaccine should be carried out. Alternatively, such individuals may be referred to an allergist for evaluation if further immunizations are to be considered.

Prior to the administration of MassBiologics’ TDVAX, the vaccine recipient’s current health status and presence of any contraindications to immunization, and any adverse events after previous immunizations to be evaluated if further immunizations are to be considered.

Prior to the administration of MassBiologics’ TDVAX, patients, parents or guardians should be informed by the health care provider of the potential for adverse reactions to the vaccine. The health care provider should inform the patient, parent, or guardian of the potential for adverse reactions.

The success of this study was due to the participation of the investigators and the willingness of the patients to take part in the study. The investigators were grateful to the patients for their cooperation and to the staff of the research centers for their assistance.

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MassBiologics’ TDVAX should not be combined through reconstitution or mixed with any other vaccine.

Table 1: Guide to Tetanus Prophylaxis in Routine Wound Management in Persons Aged 7 Years and Older

<table>
<thead>
<tr>
<th>Condition</th>
<th>Vaccine Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean, Minor Wounds</td>
<td>Td † TIG</td>
</tr>
<tr>
<td>All Other Wounds*</td>
<td>Td † TIG</td>
</tr>
</tbody>
</table>

* Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; and wounds resulting from industrial or household accidents.

† The ACIP has specific recommendations on use of Td or Tetanus Toxoid, Reduced Diphtheria Toxoids and Acellular Pertussis Vaccine (Adandoned Tdap) in adolescents and adults. ¶ Yes, if ≥10 years since the last tetanus toxoid-containing vaccine dose. § Yes, if ≥5 years since the last tetanus toxoid-containing vaccine dose. ¶§ Yes, if ≥10 years since the last tetanus toxoid-containing vaccine dose.

**tetanus toxoid-containing vaccine exists in a person who has not completed tetanus primary immunization and who has not been vaccinated with diphtheria toxoid within the previous 5 years. Consult AdP recommend- **

†‡ 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 ≥5 years since the last tetanus toxoid-containing vaccine dose. (More frequent boosters are not recommended but can occasionally be needed.)

MassBiologics’ TDVAX should not be combined through reconstitution or mixed with any other vaccine.

**ADDITIONAL INFORMATION**

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Product information as of September 2018

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