TETANUS AND DIPHTHERIA TOXOID ADSORBED

DESCRIPTION

Tetanus and Diphtheria Toxoids Adsorbed (Td) manufactured by MassBiologics is a sterile vaccine for immunization against tetanus and diphtheria. Each 0.5 ml dose of MassBiologics’ Td is formulated to contain the following active ingredients: 2 Lf of tetanus toxoid and 5 Lf of diphtheria toxoid. The tetanus and diphtheria toxoids are individually adsorbed onto aluminum phosphate. The tetanus toxoid is further purified by column chromatography. The diphtheria toxoid is further purified by column chromatography and ammonium sulfate fractionation. The diphtheria toxoid batch is selected so as to meet or exceed United States Pharmacopoeia requirements for potency.

INDICATIONS

Tetanus and Diphtheria Toxoids Adsorbed (Td) is indicated for active immunization for the prevention of tetanus and diphtheria. This vaccine is approved for use in persons 2 years of age or older.

PROHIBITED USES

Tetanus and Diphtheria Toxoids Adsorbed (Td) is contraindicated in persons with a history of a severe allergic reaction (e.g., anaphylaxis) occurring after a previous dose of this vaccine, or any component of this vaccine.

PREGNANT WOMEN

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.

FREQUENCY OF ADMINISTRATION

The Advisory Committee on Immunization Practices (ACIP) has specific recommendations on booster immunization against tetanus and diphtheria for adolescents and adults. It is not known whether MassBiologics’ Td can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MassBiologics’ Td should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

The adverse reactions that may occur following administration of MassBiologics’ Td to individuals 2 years of age and older are similar to those generally reported with diphtheria and tetanus toxoid-containing vaccines. The most common reactions are local reactions at the injection site such as tenderness, redness, and swelling, and systemic reactions such as fever, malaise, and headache.

IMMUNORESPONSE

The immune response of vaccinees to tetanus toxoid in Td can be approximated by the response to diphtheria toxoid. In clinical trials, booster doses of Td at doses of 1 Lf and 5 Lf of tetanus toxoid induced antitoxin levels greater than 0.01 antitoxin units/ml when administered to adults 26 months after the second dose.

DATA FROM CLINICAL TRIALS

POSTMARKETING REPORTS

The Advisory Committee on Immunization Practices (ACIP) has specific recommendations on booster immunization against tetanus and diphtheria for adolescents and adults. It is not known whether MassBiologics’ Td can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MassBiologics’ Td should be given to a pregnant woman only if clearly needed.

SIDE EFFECTS

The most common side effects of active immunization with tetanus and diphtheria toxoid-containing vaccine are local reactions at the injection site such as tenderness, redness, and swelling, and systemic reactions such as fever, malaise, and headache. Local reactions usually occur at the injection site within 24 hours after injection and are self-limited. Systemic reactions may occur within 24 hours after injection and may be severe in some cases.

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WARNING

Vaccination with MassBiologics’ Td may not protect all individuals.

PREPARATIONS

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The material in this vaccine is inactivated with a formaldehyde-based preserving preparation, with or without Thimerosal. Thimerosal free (TGF) vaccine is equivalent in both the concentration of the vaccine and the patient’s vaccination history (Table 1).

When reconstituted, Td (P) vaccine should be administered using a separate needle and syringe at a different anatomic site, according to the manufacturer’s package insert. If a reconstitution to using a tetanus toxoid-containing vaccine in a person who has not completed tetanus primary immunization and other than the dose, either vaccine is suspended, only passive immunization with TIG (P) (IgG) should be given.

**TABLE 1: GUIDELINES FOR ROUTINE IMMUNIZATION IN PERSONS AGED 7 YEARS AND OLDER**

<table>
<thead>
<tr>
<th>History of Tetanus Toxoid</th>
<th>Doses, Milligram</th>
<th>Other Disease Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0.5</td>
<td>No</td>
</tr>
<tr>
<td>One year</td>
<td>0.5</td>
<td>No</td>
</tr>
<tr>
<td>Two to five years</td>
<td>0.5</td>
<td>No</td>
</tr>
<tr>
<td>Six to nine years</td>
<td>1.0</td>
<td>No</td>
</tr>
<tr>
<td>Ten years or more</td>
<td>1.0</td>
<td>No</td>
</tr>
<tr>
<td>Unknown or unknown</td>
<td>1.0</td>
<td>Yes (in adults 7 years and older who have not completed tetanus primary vaccination, whose vaccination status is unknown, or who have avulsions; and wounds resulting from missiles, crushing, burns and frostbite.)</td>
</tr>
<tr>
<td>acute illness</td>
<td>1.0</td>
<td>Yes (in adults 7 years and older who have not completed tetanus primary vaccination, whose vaccination status is unknown, or who have avulsions; and wounds resulting from missiles, crushing, burns and frostbite.)</td>
</tr>
</tbody>
</table>

Such as, but not limited to, varicella vaccinated with live, killed, and subunit vaccines; and varicella resulting from encephalitis, meningitis, and herpetic keratitis.

The NPPA specifications recommend an area of size of 10 mm for Td (P) vaccine. Reconstituted Syntorx Td (P) vaccine should be administered using a separate needle and syringe at a different anatomic site, according to the manufacturer’s package insert. If a reconstitution to using a tetanus toxoid-containing vaccine in a person who has not completed tetanus primary immunization and other than the dose, either vaccine is suspended, only passive immunization with TIG (P) (IgG) should be given.

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

### HOW SUPPLIED

The material in this unit is to be used only by properly trained personnel.

- MassBiologics’ Td (P) vaccine is supplied in a package of 10 single dose vials.
- MassBiologics’ Td (P) vaccine should not be combined through reconstitution or mixed with any other vaccine.
- Td 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.

### ADMINISTRATION

* Do not use vaccine after expiration date.
* Store at 2°C - 8°C (36°F - 46°F). DO NOT FREEZE. Discard product if exposed to freezing.
* NDC No. 13533-131-01 is the code for the package containing ten vials.
* NDC No. 13533-131-00 is the code for individual single dose (0.5ml) vials.
* 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.

### REFERENCES