*Sections or subsections omitted from the full prescribing information are not listed

**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE

TENIVAC® is a vaccine indicated for active immunization for the prevention of tetanus and diphtheria in persons 7 years of age and older. (1)

2 DOSAGE AND ADMINISTRATION

2.1 Primary Immunization

Each 0.5 mL dose should be administered intramuscularly. (2.5)

Primary immunization with TENIVAC consists of 3 doses. The first 2 doses are administered 2 months apart and the third dose is administered 6-8 months after the second dose. (2.1)

TENIVAC may be used for booster immunization against tetanus and diphtheria. Routine booster immunization against tetanus and diphtheria is recommended at 11-12 years of age and every 10 years thereafter. (2.2)

For post-exposure diphtheria prophylaxis and for management of a tetanus prone wound, a booster dose of TENIVAC may be administered if at least 5 years have elapsed since previous receipt of a diphtheria toxoid and tetanus toxoid containing vaccine. (2.3) (2.4)

2.2 Routine Booster Immunization

TENIVAC may be used for routine booster immunization against tetanus and diphtheria in persons 7 years of age and older. (2.2, 2.3, 2.4) may be associated with increased incidence and severity of adverse reactions. (5.3)

Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of a tetanus toxoid-containing vaccine should not receive TENIVAC more frequently than every 10 years, even for tetanus prophylaxis as part of wound management. (5.4)

Carefully consider benefits and risks before administering TENIVAC to persons with a history of Guillain-Barré syndrome within 6 weeks of a previous tetanus toxoid-containing vaccine. (5.5)

Syncopal (fainting) has been reported following vaccination with TENIVAC. Procedures should be in place to avoid injury from fainting. (5.8)

2.3 Diphtheria Prophylaxis for Case Contacts

The most frequent solicited injection site reaction within 0-3 days following TENIVAC was pain, reported in 78.3% of study participants 11-59 years of age and 35.3% of participants ≥60 years of age. (6.1)

The most frequent solicited systemic reaction within 0-3 days following TENIVAC was headache, reported in 17.9% of participants, overall. (6.1)

Other common (>10%) solicited adverse reactions within 0-3 days following TENIVAC were injection site redness, injection site swelling, malaise, muscle weakness and pain in joints. (6.1)

2.4 Tetanus Prophylaxis in Wound Management

No safety and immunogenicity data are available on the concomitant administration of TENIVAC with other US licensed vaccines. (7.1)

If passive protection against tetanus is required, Tetanus Immune Globulin (TIG) (Human) may be administered concomitantly at a separate site with a separate needle and syringe. (7.2)

Immunosuppressive therapies may reduce the immune response to TENIVAC. (7.3)

3 DOSAGE FORMS AND STRENGTHS

Suspension for injection supplied in 0.5 mL single-dose vials or syringes. (3)

4 CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) to a previous dose of TENIVAC, or any other tetanus and diphtheria toxoid-containing vaccine, or any component of this vaccine. (4.1)

5 WARNINGS AND PRECAUTIONS

The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. (5.2)

6 ADVERSE REACTIONS

The most frequent solicited injection site reaction within 0-3 days following TENIVAC was pain, reported in 78.3% of study participants 11-59 years of age and 35.3% of participants ≥60 years of age. (6.1)

The most frequent solicited systemic reaction within 0-3 days following TENIVAC was headache, reported in 17.9% of participants, overall. (6.1)

Other common (>10%) solicited adverse reactions within 0-3 days following TENIVAC were injection site redness, injection site swelling, malaise, muscle weakness and pain in joints. (6.1)

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

7.2 Tetanus Immune Globulin (Human)

7.3 Immunosuppressive Treatments

8 USE IN SPECIFIC POPULATIONS

Pre- and post-vaccination tetanus and diphtheria seroprotection rates were lower in study participants ≥65 years of age compared to younger participants. In general, rates of solicited adverse reactions were not higher in participants ≥65 years of age compared to younger participants. (8.5)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 12/2022
The need for active immunization with a tetanus toxoid-containing preparation, with or without passive immunization with Tetanus Immune Globulin (TIG). (Human) depends on both the condition of the wound and the patient’s vaccination history. (See Table 1.)

When indicated, TIG (Human) should be administered at a separate site, with a separate needle and syringe, according to the manufacturer’s package insert. If a contraindication to using tetanus toxoid-containing preparations exists in a person who has not completed a primary immunizing course of tetanus toxoid and other than a clean, minor wound is sustained, only passive immunization with TIG (Human) should be given. (1)

### Table 1: Guide for use of Tetanus and Diphtheria Toxoids Adsorbed (Td) for Tetanus Prophylaxis in Routine Wound Management in Persons 7 Years of Age and Older

<table>
<thead>
<tr>
<th>History of Adsorbed Tetanus Toxoid</th>
<th>Clean, Minor Wounds</th>
<th>Clean, Minor Wounds TIG</th>
<th>All Other Wounds</th>
<th>All Other Wounds TIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown or &lt; 3 doses</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>≥ 3 doses1</td>
<td>No2</td>
<td>No2</td>
<td>No</td>
<td>No2</td>
</tr>
</tbody>
</table>

1Such as, but not limited to, wounds contaminated with dirt, puncture wounds and traumatic wounds. If only three doses of fluid tetanus toxoid have been received, then a fourth dose of toxoid, preferably an adsorbed toxoid should be given.

2Yes, if >5 years since last dose. (More frequent boosters are not needed and can accentuate side effects.)

### 5.2 Administration

Just before use, shake the single-dose vial or syringe well until a uniform, white, cloudy suspension results. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If these conditions exist, the product should not be administered.

Administer the 0.5 mL dose of TENIVAC intramuscularly. Discard unused portion.

If TENIVAC is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained. (See Drug Interactions (7.3).)

### 5.3 Frequency of Administration

More frequent doses of TENIVAC than described in Section 2, Dosage and Administration, may be associated with increased incidence and severity of adverse reactions. (See Dosage and Administration (2.1, 2.2, 2.3, 2.4).)

### 5.4 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 TENIVAC more frequently than every 10 years, even for tetanus prophylaxis as part of wound management.

### 5.5 Guillain-Barré Syndrome and Brachial Neuritis

A review by the Institute of Medicine found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. (2) If Guillain-Barré syndrome occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give TENIVAC or any vaccine should not be based on these studies alone, as there is not sufficient evidence of a causal relationship. (See Table 2.)

### 5.6 Limitations of Vaccine Effectiveness

Vaccination with TENIVAC may not protect all individuals. (3) Tenivac is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained. (See Drug Interactions (7.3).)

### Table 2: Frequency and Severity of Selected Solicited Adverse Events Within 0–3 Days Following TENIVAC or DECAVAC in a US Study

<table>
<thead>
<tr>
<th>Injection Site Adverse Reactions</th>
<th>TENIVAC Adolescents 11 to 18 years N = 491–492 %</th>
<th>TENIVAC Adults 19 to 59 years N = 247 %</th>
<th>TENIVAC Adults ≥ 60 years N = 668–695 %</th>
<th>DECAVAC Adults ≥ 60 years N = 666–693 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Yes: 80.1</td>
<td>74.9</td>
<td>35.3</td>
<td>29.4</td>
</tr>
<tr>
<td>No</td>
<td>15.0</td>
<td>18.2</td>
<td>2.9</td>
<td>2.3</td>
</tr>
<tr>
<td>Severe1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>Redness</td>
<td>Any: 7.3</td>
<td>3.2</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>≤ 35 mm to &lt;50 mm</td>
<td>1.2</td>
<td>2.4</td>
<td>0.7</td>
<td>1.3</td>
</tr>
<tr>
<td>≥ 50 mm</td>
<td>0.4</td>
<td>0.4</td>
<td>2.3</td>
<td>1.9</td>
</tr>
<tr>
<td>Swelling</td>
<td>Any: 7.6</td>
<td>5.2</td>
<td>1.7</td>
<td>1.3</td>
</tr>
<tr>
<td>≤ 35 mm to &lt;50 mm</td>
<td>1.2</td>
<td>2.8</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>≥ 50 mm</td>
<td>1.8</td>
<td>2.8</td>
<td>1.7</td>
<td>1.3</td>
</tr>
</tbody>
</table>

### 6.1 Clinical Trials Experience

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. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to vaccine use and for approximating rates of these events. (7.1, 7.2, 7.3)

In a primary immunization study conducted in Canada, 18 participants, 8 of whom were 6 to 9 years of age and 10 of whom were 17 to 56 years of age, received three doses of TENIVAC. In four booster immunization studies conducted in either the US or Canada, TENIVAC was administered to 3,723 participants overall, ranging in age from 11 to 93 years.
Table 2: Frequency and Severity of Selected Adverse Events Within 0–3 Days Following TENIVAC or DECAVAC in a US Study (continued)

<table>
<thead>
<tr>
<th></th>
<th>TENIVAC Adults</th>
<th>TENIVAC Adolescents</th>
<th>DECAVAC Adults</th>
<th>DECAVAC Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 to 18 years</td>
<td>N = 491-492</td>
<td>N = 247</td>
<td>N = 688-695</td>
<td>N = 688-693</td>
</tr>
<tr>
<td>N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>2.8</td>
<td>1.6</td>
<td>2.2</td>
<td>1.4</td>
</tr>
<tr>
<td>Severe*</td>
<td>0.6</td>
<td>0.4</td>
<td>0.1</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Severe: incapacitating, unable to perform usual activities, may have/or required medical care or absenteemis.

In the US booster immunization study, among participants ≥60 years of age, 7 (1.0%) participants in the TENIVAC group and 10 (1.4%) participants in the DECAVAC group experienced a serious adverse event within 30 days following vaccination. During this period, 2 (0.3%) participants 19-59 years of age and no participants 11-18 years of age experienced a serious adverse event following TENIVAC. Serious adverse events within 30 days following TENIVAC included localized infection, asthma, colonic poly, cellulitis, angina pectoris, hip and wrist fracture, cholecystitis, chest pain and cerebrovascular accident. There were five deaths reported during the study. All of the reported deaths were in participants ≥60 years of age and occurred >30 days post-vaccination: three in the TENIVAC group (cardiopulmonary arrest; myocardial infarction and septic shock; and unknown cause) and two in the DECAVAC group (myocardial infarction and congestive heart failure; and liver cancer). In the primary immunization study (N = 18) in which serious adverse events were monitored for 3 days following each vaccination and in three other booster immunization studies in which serious adverse events were monitored for either four days (N = 347) or one month (N = 426) following vaccination, no serious adverse events were reported.

6.2 Postmarketing Experience

The following adverse events have been spontaneously reported during the postmarketing use of TENIVAC. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. The following adverse events were included based on severity, frequency of reporting or the strength of causal association to TENIVAC:

- Blood and lymphatic system disorders
  - Lymphadenopathy
- Immune system disorders
  - Allergic reactions (such as erythematous rash, maculopapular rash, urticaria and pruritus);
  - anaphylactic reaction (bronchospasm and angioedema);
- Nervous system disorders
  - Aesthesia, dizziness, syncope;
  - Guillain-Barré syndrome
- Gastrointestinal disorders
  - Vomiting;
- Musculoskeletal, connective tissue and bone disorders
  - Myalgia, pain in extremities;
- General disorders and administration site conditions
  - Injection site reactions (including inflammation, mass, edema, induration, warmth, pruritus, cellulitis, discomort);

Fatigue, edema peripheral

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

No safety and immunogenicity data are available on the concomitant administration of TENIVAC with other US licensed vaccines.

7.2 Tetanus Immune Globulin (Human)

If passive protection against tetanus is required, TIG (Human) may be administered according to its prescribing information, concomitantly with TENIVAC at a separate site with a separate needle and syringe. [See Dosage and Administration (2.4)].

7.3 Immunosuppressive Treatments

Immunosuppressive therapies, including irradiation, antimitabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to TENIVAC. [See Warnings and Precautions (5.7)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no adequate and well-controlled studies of TENIVAC in pregnant women in the U.S. There are insufficient human data from TENIVAC administered during pregnancy to establish the presence or absence of a vaccine-associated risk.

A developmental toxicity study has been performed in female rabbits administered a single human dose of TENIVAC prior to mating and during gestation. This study revealed no evidence of harm to the fetus due to TENIVAC. [See Animal (data)]

Data

Animal data

In a developmental toxicity study, female rabbits received a single human dose (0.5 mL) of TENIVAC by intramuscular injection 17 and 10 days prior to mating, and on gestation days 6 and 8. No adverse effects on pre-weaning development up to post-natal day 35 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

It is not known whether TENIVAC components are excreted in human milk. Data are not available to assess the effect of administration of TENIVAC on breastfed infants or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for TENIVAC and any potential adverse effects on the breastfed child from TENIVAC or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

TENIVAC is not approved for use in infants and children younger than 7 years of age. Safety and effectiveness of TENIVAC in this age group have not been established.

8.5 Geriatric Use

In one clinical study, (TDC01) 449 participants 65 years of age and over, including 192 participants who were 75 years of age and over received a dose of TENIVAC. A lower proportion of participants 65 years of age and over had a pre-vaccination seroprotective level of antibody to tetanus toxoid and diphtheria toxin compared to adolescents and adults less than 65 years of age. The proportion of participants 65 years of age and over with a seroprotective level of antibody following TENIVAC was marginally lower for tetanus and lower for diphtheria compared to younger participants. In general, rates of solicited adverse events were not higher in participants 65 years of age and over compared to younger participants. [See Adverse Reactions (6), Clinical Pharmacology (12.1), and Clinical Studies (14.2)].

11 DESCRIPTION

TENIVAC, Tetanus and Diphtheria Toxoids Adsorbed, is a sterile isotonic suspension of tetanus and diphtheria toxoids adsorbed on aluminum phosphate. Each 0.5 mL dose of TENIVAC contains the following active ingredients:

- Tetanus Toxoid
  - 5 LI
- Diphtheria Toxoid
  - 2 LI

Other ingredients per 0.5 mL dose include 1.5 mg of aluminum phosphate (0.33 mg of aluminum) as the adjuvant and ≤5.0 μg of residual formaldehyde.

Clostridium tetani is grown in modified Mueller-Miller casamino acid medium without beef heart infusion. (3) Tetanus toxin is detoxified with formaldehyde and purified by ammonium sulfate fractionation and dialfiltration. Corynebacterium diphtheriae is grown in modified Mueller’s growth medium. (4) After purification by ammonium sulfate fractionation, diphtheria toxin is detoxified with formaldehyde and dialfiltrated. Tetanus and diphtheria toxoids are individually adsorbed onto aluminum phosphate.

The adsorbed toxoid and diphtheria toxoids are combined with aluminum phosphate (as adjuvant), sodium chloride and water for injection. This product contains no preservative.

In the guinea pig potency test, the tetanus toxoid component induces at least 2 neutralizing units/mL of serum and the diphtheria toxoid component induces at least 0.5 neutralizing units/mL of serum. The tip caps of the prefilled syringes may contain natural rubber latex. The vial stoppers do not contain latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tetanus

Tetanus is an acute 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 at least 0.1 IU/mL, measured by neutralization assay is considered the minimum protective level. (5) A tetanus antitoxin level ≥0.1 IU/mL is measured by the ELISA used in some clinical studies of TENIVAC is considered protective.

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 0.1 IU/mL is the lowest level giving some degree of protection. Antitoxin levels of at least 0.1 IU/mL are generally regarded as protective. (5) A level of at least 1.0 IU/mL has been associated with long-term protection. (7)

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

TENIVAC has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility in animals. Vaccination of female rabbits with TENIVAC had no effects on fertility. [See Use in Specific Populations (8.1)].

14 CLINICAL STUDIES

14.1 Primary Immunization

A three-dose primary immunization series with TENIVAC was evaluated in 17 participants ages 6 to 56 years in a study conducted in Canada. [See Adverse Reactions (6.1)]. The first two doses were administered two months apart, followed by a third dose six to eight months after the second dose. Serum tetanus antitoxin levels were measured by an in vivo neutralizing assay and serum diphtheria antitoxin levels were measured by an in vitro neutralizing assay. [See Clinical Pharmacology (12.1)]. All 17 participants had serum tetanus and diphtheria antitoxin levels pre-vaccination and 7 days post-vaccination >0.01 IU/mL, consistent with no previous immunization. Four weeks following the second dose, all 17 participants had a serum tetanus antitoxin level ≥0.1 IU/mL, and a serum diphtheria antitoxin level ≥0.01 IU/mL. Four weeks following the third dose, all 17 participants had a serum diphtheria antitoxin level ≥0.1 IU/mL.

14.2 Booster Immunization

In the US multicenter booster immunization study (TDC01) [see Adverse Reactions (6.1)], the immune response to a dose of TENIVAC was evaluated in an open-label manner in a subset of participants 11 to 59 years of age, and in comparison to DECAVAC in participants ≥60 years of age who were randomized to receive a dose of either TENIVAC or DECAVAC. Tetanus immune responses, measured by ELISA [see Clinical Pharmacology (12.1)] are presented in Table 3. Diphtheria immune responses, measured by a microneutralization assay [see Clinical Pharmacology (12.1)], are presented in Table 4.

Among adults 65 years of age and over who received TENIVAC (N = 419), 94.5% (95% confidence interval 91.9, 96.5) had a post-vaccination tetanus antitoxin level ≥0.1 IU/mL and 61.1% (95% confidence interval 56.2, 65.8) had a post-vaccination diphtheria antitoxin level ≥0.1 IU/mL.
### Table 3: Tetanus Antitoxoid Levels and Booster Response Rates Following a Dose of TENIVAC, by Age Group, and for Adults ≥60 Years of Age, Compared to DECAVAC, per Protocol Immunogenicity Population

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Age Group</th>
<th>Timing</th>
<th>Percent of Participants With Specified Level of Tetanus Antitoxoid and Booster Response</th>
<th>Percent of Participants With Specified Level of Tetanus Antitoxoid and Booster Response</th>
<th>Percent of Participants With Specified Level of Tetanus Antitoxoid and Booster Response</th>
<th>Percent of Participants With Specified Level of Tetanus Antitoxoid and Booster Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>TENIVAC</td>
<td>Adolescents 11 to 18 years (N = 470)</td>
<td>Pre</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults 19 to 59 years (N = 237)</td>
<td>Post</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults ≥60 years (N = 661)</td>
<td>Pre</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults ≥60 years (N = 658)</td>
<td>Post</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
</tr>
<tr>
<td>DECAVAC</td>
<td>Adults ≥60 years (N = 658)</td>
<td>Pre</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
<td>≥0.1 IU/mL % (95% CI)</td>
</tr>
</tbody>
</table>

Pre-indicates pre-vaccination bleed.
Post-indicates 26–42 days post-vaccination bleed.
*Booster response: If pre-vaccination level ≥0.10 IU/mL, 4-fold increase and post-vaccination level ≥0.10 IU/mL. If pre-vaccination level >0.10 IU/mL and ≤0.2 IU/mL, 4-fold increase. If pre-vaccination level >2.7 IU/mL, 2-fold increase.
†TENIVAC non-inferior to DECAVAC (upper limit of 95% CI for difference (DECAVAC minus TENIVAC) <5%)
‡Non-inferiority criteria not prospectively specified for this endpoint.
§TENIVAC non-inferior to DECAVAC (upper limit of 95% CI for difference (DECAVAC minus TENIVAC) <10%).

### Table 4: Diphtheria Antitoxin Levels and Booster Response Rates Following a Dose of TENIVAC, by Age Group, and for Adults ≥60 Years of Age, Compared to DECAVAC, per Protocol Immunogenicity Population (continued)

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Age Group</th>
<th>Timing</th>
<th>Percent of Participants With Specified Level of Diphtheria Antitoxin and Booster Response</th>
<th>Percent of Participants With Specified Level of Diphtheria Antitoxin and Booster Response</th>
<th>Percent of Participants With Specified Level of Diphtheria Antitoxin and Booster Response</th>
<th>Percent of Participants With Specified Level of Diphtheria Antitoxin and Booster Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>TENIVAC</td>
<td>Adolescents 11 to 18 years (N = 470)</td>
<td>Pre</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults 19 to 59 years (N = 237)</td>
<td>Post</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults ≥60 years (N = 661)</td>
<td>Pre</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Adults ≥60 years (N = 658)</td>
<td>Post</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
</tr>
<tr>
<td>DECAVAC</td>
<td>Adults ≥60 years (N = 658)</td>
<td>Pre</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
<td>≥0.01 IU/mL % (95% CI)</td>
</tr>
</tbody>
</table>

Pre-indicates pre-vaccination bleed.
Post-indicates 26–42 days post-vaccination bleed.
*Booster response: If pre-vaccination level ≤0.10 IU/mL, 4-fold increase and post-vaccination level ≥0.10 IU/mL. If pre-vaccination level >0.10 IU/mL and ≤2.56 IU/mL, 4-fold increase. If pre-vaccination level >2.56 IU/mL, 2-fold increase.
†TENIVAC non-inferior to DECAVAC (upper limit of 95% CI for difference (DECAVAC minus TENIVAC) <5%)
‡Non-inferiority criteria not prospectively specified for this endpoint.
§TENIVAC non-inferior to DECAVAC (upper limit of 95% CI for difference (DECAVAC minus TENIVAC) <10%).

### REFERENCES

8. HOW SUPPLIED/STORAGE AND HANDLING

Single-dose Syringe, NDC No. 49281-215-88; in package of 10 syringes, NDC No. 49281-215-15. The tip caps of the prefilled syringes may contain natural rubber latex. No other components contain latex. TENIVAC should be stored at 2°C to 8°C (35°F to 46°F). DO NOT FREEZE. Product which has been exposed to freezing should not be used. Do not use after expiration date shown on the label.

17 PATIENT COUNSELING INFORMATION

Before administration of TENIVAC health-care providers should inform the patient, parent or guardian of the benefits and risks of the vaccine and the importance of completing the primary immunization series or receiving recommended booster doses, as appropriate, unless a contraindication to further immunization exists.

The health-care provider should inform the patient, parent or guardian about the potential for adverse reactions that have been temporally associated with TENIVAC or other vaccines containing similar components. The health-care provider should provide the Vaccine Information Statements (VISs) which are required by the National Childhood Vaccine Injury Act of 1986 to be given with each immunization. Patients, parents, or guardians should be instructed to report adverse reactions to their health-care provider.

Manufactured by:
Sanofi Pasteur Limited
Toronto Ontario Canada

Distributed by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

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