HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DECAVAC (Tetanus and Diphtheria Toxoids Adsorbed) safely and effectively. See full prescribing information for DECAVAC®.

DECAVAC® (Tetanus and Diphtheria Toxoids Adsorbed)
Suspension for Intramuscular Injection
Initial US Approval: 1955

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.2) [01/2011]

----------INDICATIONS AND USAGE----------
DECAVAC is a vaccine indicated for active immunization for the prevention of tetanus and diphtheria. DECAVAC is approved for use in persons 7 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- Each 0.5 mL dose should be administered intramuscularly. (2.1)
- Primary immunization consists of 3 doses. The first two doses are administered at least 4 weeks apart and the third dose is administered at least 6 months after the second dose. (2.1)
- Routine booster immunization against tetanus and diphtheria is recommended at 11-12 years of age and every 10 years thereafter. (2.1)

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

----------CONTRAINDICATIONS----------
- Severe allergic reaction (eg, anaphylaxis) after a previous dose of DECAVAC or any other tetanus toxoid or diphtheria toxoid containing vaccine or any other component of this vaccine. (4.1)

----------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)
- More frequent administration of DECAVAC than described in Dosage and Administration 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 DECAVAC less than 10 years since the last dose of tetanus toxoid-containing vaccine, even for tetanus prophylaxis as part of wound management. (5.4)
- If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following DECAVAC. (5.5)

----------ADVERSE REACTIONS----------
- The most frequent solicited injection site reaction following DECAVAC was pain, reported in 71% of adolescents 11-17 years of age and in 63% of adults 18-64 years of age. (6.1)
- The most frequent solicited systemic adverse event following DECAVAC was headache, reported in 40% of adolescents 11-17 years of age and in 34% of adults 18-64 years of age. (6.1)
- Injection site swelling, injection site erythema, body ache or muscle weakness, tiredness, and diarrhea also were reported commonly (≥10%) in both age groups; chills, nausea, and sore and swollen joints were reported commonly (≥ 10%) in adolescents. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- No safety and immunogenicity data are available on concomitant administration of DECAVAC with other US licensed vaccines. (7.1)
- Immunosuppressive therapies may reduce the immune response to DECAVAC. (7.2)

See **17 PATIENT COUNSELING INFORMATION**.
Revised: March 2011.

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION:

1. INDICATIONS AND USAGE

DECAVAC® is a vaccine indicated for active immunization for the prevention of tetanus and diphtheria. DECAVAC vaccine is approved for use in persons 7 years of age and older.

2. DOSAGE AND ADMINISTRATION

2.1. Dosage and Schedule

Primary Immunization

DECAVAC vaccine may be used in persons 7 years of age and older who have not been immunized previously against tetanus and diphtheria or who have begun a primary immunization series but did not complete it. The primary immunization series consists of three 0.5 mL doses. The first two doses are administered at least 4 weeks apart and the third dose is administered at least 6 months after the second dose.

DECAVAC vaccine may be used to complete the primary immunization series for tetanus and diphtheria in persons 7 years of age or older who have received 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). However, the safety and efficacy of DECAVAC vaccine in such regimens have not been evaluated.

Routine Booster Immunization

DECAVAC vaccine 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. (1)

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. (2) DECAVAC vaccine 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. (2)

Table 1: Guide to Use of Tetanus and Diphtheria Toxoids Adsorbed (Td) and Tetanus Immune Globulin (TIG) (Human) for Tetanus Prophylaxis in Routine Wound Management for Persons 7 Years of Age and Older

History of Adsorbed Tetanus Toxoid (doses)	Clean, Minor Wounds		All Other Wounds[a]	
	Td	TIG	Td	TIG
Unknown or <three	Yes	No	Yes	Yes
≥three[b]	No[c]	No	No[d]	No

[a]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.

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

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

[d]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

DECAVAC vaccine 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. (2)

2.2. Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If these conditions exist, DECAVAC vaccine should not be administered.

DECAVAC vaccine, after shaking, is a turbid liquid, whitish-gray in color.

For DECAVAC vaccine supplied in vials, shake the vial well before withdrawing the dose. Discard vial if DECAVAC vaccine cannot be resuspended.

For DECAVAC vaccine supplied in syringes, shake the syringe well before administering the dose. Discard syringe if DECAVAC vaccine cannot be resuspended.

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

Do not administer DECAVAC vaccine intravenously or subcutaneously.

DECAVAC vaccine should not be combined through reconstitution or mixed with any other vaccine.

3. DOSAGE FORMS AND STRENGTHS

DECAVAC vaccine is a sterile suspension for injection available in 0.5 mL single-dose vials or syringes.

4. CONTRAINDICATIONS

4.1. Hypersensitivity

A severe allergic reaction (eg, anaphylaxis) after a previous dose of DECAVAC vaccine or any other tetanus toxoid or diphtheria toxoid containing vaccine or any other component of this vaccine is a contraindication to administration of DECAVAC vaccine. [See *Description (11).*] Because of uncertainty as to which component of the vaccine may 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.

5. WARNINGS AND PRECAUTIONS

5.1. Management of Acute Allergic Reactions

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

5.2. Latex

The tip caps of the DECAVAC prefilled syringes may contain natural rubber latex, which may cause allergic reactions in latex-sensitive individuals.

5.3. Frequency of Administration

More frequent administration of DECAVAC vaccine than described in Dosage and Administration [see *Dosage and Administration (*2.1*)*] may be associated with increased incidence and severity of adverse reactions.

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 DECAVAC vaccine more frequently than every 10 years, even for tetanus prophylaxis as part of wound management [see *Dosage and Administration (*2.1*)*].

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. (3) If Guillain-Barré syndrome occurred within 6 weeks after receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following DECAVAC vaccine.

5.6. Limitations of Vaccine Effectiveness

Vaccination with DECAVAC vaccine may not protect all individuals.

5.7. Altered Immunocompetence

Immune responses to inactivated vaccines and toxoids when given to immunocompromised persons may be suboptimal. The immune response to DECAVAC vaccine administered to immunocompromised individuals (whether from disease or treatment) has not been studied.

6. ADVERSE REACTIONS

6.1. Data from Clinical Studies

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.

6.2. Primary Immunization

In a clinical study, 42 persons 6-58 years of age underwent primary immunization against tetanus and diphtheria. Eight of these participants (19%) noted local reactions consisting of pain and tenderness, induration, and erythema at the injection site; none reported systemic symptoms. (4)

6.3. Booster Immunization

In a clinical study, 792 adolescents 11-17 years of age and 573 adults 18-64 years of age received a booster dose with DECAVAC vaccine. Study participants had not received tetanus or diphtheria toxoid-containing vaccines within the previous 5 years. Solicited local reactions and systemic adverse events were monitored daily for 14 days post-vaccination using subject diary cards.

Serious adverse events were monitored through 6 months post-vaccination. Ninety-seven percent of participants who received DECAVAC vaccine completed the 6-month telephone follow-up.

Solicited Adverse Events

The frequency of selected solicited injection site reactions (pain, swelling, or erythema) occurring during Days 0-14 following booster vaccination with DECAVAC vaccine in adolescents 11 through 17 years of age, and adults 18 through 64 years of age are presented in Table 2. Pain at the injection site was the most common adverse reaction occurring in 71% of adolescents and 62.9% of adults.

Table 2: Frequencies of Solicited Injection Site Reactions for Adolescents and Adults, Days 0-14 Following BoosterVaccination with DECAVAC Vaccine

Adverse Event		Adolescents 11-17 years N[a] = 783-787 (%)	Adults 18-64 years N[a] = 551-561 (%)
Injection Site Pain	Any	71.0	62.9
	Moderate[b]	15.6	10.2
	Severe[c]	0.6	0.9
Injection Site Swelling	Any	18.3	17.3
	Moderate		
	1.0 to 3.4 cm	5.7	5.4
	Severe		
	≥3.5 cm	5.5	5.5
	≥5 cm	3.6	2.7
Injection Site Erythema	Any	19.7	21.6
	Moderate		
	1.0 to 3.4 cm	4.6	8.4
	Severe		
	≥3.5 cm	5.3	4.8
	≥5 cm	2.9	3.0

[a]N = number of participants who provided data (not all participants evaluated every event).

[b]Interfered with activities, but did not necessitate medical care or absenteeism.

[c]Incapacitating, prevented the performance of usual activities, may have/or did necessitate medical care or absenteeism.

The frequency of solicited systemic adverse events occurring during Days 0-14 following booster vaccination with DECAVAC vaccine are presented in Table 3. Headache was the most frequent solicited systemic adverse event, and was usually of mild or moderate intensity.

Table 3: Frequencies of Solicited Systemic Adverse Events for Adolescents and Adults, Days 0-14 Following Booster Vaccination with DECAVAC Vaccine

Adverse Event		Adolescents 11-17 years N[a] = 787 (%)	Adults 18-64 years N[a] = 560-561 (%)
Headache	**Any**	40.4	34.1
	Moderate[b]	11.1	10.5
	Severe[c]	1.5	2.1
Body Ache or Muscle Weakness	**Any**	29.9	18.8
	Moderate[b]	6.9	5.7
	Severe[c]	0.9	0.9
Tiredness	**Any**	27.3	20.7
	Moderate[b]	7.5	6.1
	Severe[c]	1.0	0.5
Chills	**Any**	12.6	6.6
	Moderate[b]	2.5	1.6
	Severe[c]	0.1	0.5
Nausea	**Any**	12.3	7.9
	Moderate[b]	3.2	1.8
	Severe[c]	0.6	0.5
Sore and Swollen Joints	**Any**	11.7	7.0
	Moderate[b]	2.5	2.1
	Severe[c]	0.1	0.5
Diarrhea	**Any**	10.2	11.3
	Moderate[b]	2.0	2.7
	Severe[c]	0.0	0.5
Lymph Node Swelling	**Any**	5.3	4.1
	Moderate[b]	0.5	0.5
	Severe[c]	0.0	0.0
Vomiting	**Any**	2.8	1.8
	Moderate[b]	1.1	0.9
	Severe[c]	0.3	0.2
Fever	**Any ≥38.0°C (≥100.4°F)**	2.7	1.1
	≥38.8°C to ≤39.4°C (≥102.0°F to ≤103.0°F)	0.6	0.2
	≥39.5°C (≥103.1°F)	0.1	0.2
Rash	**Any**	2.0	2.3

[a]N = number of participants who provided data (not all participants evaluated every event).

[b]Interfered with activities, but did not necessitate medical care or absenteeism.

[c]Incapacitating, prevented the performance of usual activities, may have/or did necessitate medical care or absenteeism.

Serious Adverse Events

Among 792 adolescents 11-17 years of age and 573 adults 18-64 years of age who received a booster dose with DECAVAC vaccine, 2 adolescents and 2 adults reported a serious adverse event that occurred within 30 days following vaccination. Events reported in adolescents were jaw fracture secondary to trauma and abdominal pain/appendectomy. Events reported in adults were atrial septal defect and elective surgical repair in one subject, and myocardial infarction in one subject with a history of coronary artery disease.

6.4. Post-Marketing Experience

The following adverse events have been spontaneously reported during the post-marketing use of Td manufactured by Sanofi Pasteur Inc. 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 vaccination. The following adverse events were included based on severity, frequency of reporting or the strength of causal association with DECAVAC vaccine.

- *Blood and Lymphatic System Disorders*

  Lymphadenopathy.

- *Immune System Disorders*

  Allergic reactions (such as rash, urticaria, pruritus, and angioedema), including anaphylactic reactions.

- *Nervous System Disorders*

Headache, paresthesia, dizziness, syncope, and convulsions.

- *Gastrointestinal Disorders*

  Nausea, vomiting.

- *Musculoskeletal, Connective Tissue and Bone Disorders*

  Myalgia, arthralgia, pain in extremities, musculoskeletal stiffness.

- *General Disorders and Administration Site Conditions*

  Injection site reactions (including swelling, redness, warmth, induration, cellulitis, and nodules).

  Pyrexia, chills, pain, malaise, asthenia, fatigue, edema peripheral.

7. DRUG INTERACTIONS

7.1. Concomitant Administration with Other Vaccines

No safety and immunogenicity data are available regarding concomitant administration of DECAVAC vaccine with other US licensed vaccines.

7.2. Immunosuppressive Treatments

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to DECAVAC vaccine.

7.3. Tetanus Immune Globulin (Human)

If passive protection against tetanus is required, TIG (Human) may be administered according to its prescribing information, concomitantly with DECAVAC vaccine at a separate site with a separate needle and syringe. [See *Dosage and Administration (*2.1*).*]

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Pregnancy Catergory C: Animal reproduction studies have not been conducted with DECAVAC vaccine. It is also not known whether DECAVAC vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DECAVAC vaccine should be given to a pregnant woman only if clearly needed.

8.3. Nursing Mothers

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

8.4. Pediatric Use

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

8.5. Geriatric Use

Clinical studies of DECAVAC vaccine did not include subjects aged 65 years and over to determine whether they respond differently than younger subjects.

11. DESCRIPTION

DECAVAC vaccine, Tetanus and Diphtheria Toxoids Adsorbed, for intramuscular injection, is a sterile suspension of alum (aluminum potassium sulfate)-precipitated toxoids in an isotonic sodium chloride solution. The vaccine, after shaking, is a turbid liquid, whitish-gray in color.

Corynebacterium diphtheriae cultures are grown in a modified Mueller and Miller medium. (5) *Clostridium tetani* cultures are grown in a peptone-based medium containing an extract of bovine muscle tissue. The bovine muscle tissue used in this medium is US sourced. Tetanus and diphtheria toxins produced during the growth of the cultures are detoxified with formaldehyde. The detoxified materials are then separately purified by serial ammonium sulfate fractionation and diafiltration, and adsorbed onto alum.

Each 0.5 mL dose of DECAVAC vaccine is formulated to contain the following active ingredients: 5 Lf of tetanus toxoid and 2 Lf of diphtheria toxoid. The tetanus and diphtheria toxoids induce at least 2 units and 0.5 units of antitoxin per mL of serum, respectively, in the guinea pig potency test. Each 0.5 mL dose also contains a trace amount of thimerosal [mercury derivative, (≤0.3 mcg mercury/dose) not as a preservative] from the manufacturing process, aluminum potassium sulfate adjuvant (not more than 0.28 mg aluminum by assay), and not more than 100 mcg (0.02%) of residual formaldehyde.

The tip caps of the prefilled syringes may contain natural rubber latex. No other components of any presentation contain latex.

12. CLINICAL PHARMACOLOGY

12.1. Tetanus

Tetanus is an acute and 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 by neutralization assays, is considered the minimum protective level. (6) (7) A tetanus antitoxoid level ≥0.1 IU/mL as measured by the enzyme-linked immunosorbent assay (ELISA) used in the booster immunization study of DECAVAC vaccine is considered protective [see *Clinical Studies (*14.2*)*].

12.2. 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. (7) (8) A diphtheria antitoxin level of 0.1 IU/mL is generally regarded as protective. (8) Diphtheria antitoxin levels of ≥1.0 IU/mL have been associated with long-term protection. (8) Antibodies to diphtheria toxin were measured by a microneutralization assay in the booster immunization study of DECAVAC vaccine [see *Clinical Studies (*14.2*)*].

13. NON-CLINICAL TOXICOLOGY

13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed with DECAVAC vaccine to evaluate carcinogenicity, mutagenic potential, or impact on fertility.

14. CLINICAL STUDIES

14.1. Primary Immunization

The effectiveness of primary immunization with tetanus toxoid and diphtheria toxoid used in DECAVAC vaccine was determined on the basis of an immunogenicity study, with a comparison to a serological correlate of protection (0.01 antitoxin units/mL) established by the Panel on Review of Bacterial Vaccines & Toxoids. (7) A clinical study to evaluate the serological responses was performed in 58 individuals 6-58 years of age. Of these, 46 persons had no evidence of prior immunity to tetanus toxin and 47 persons had no evidence of prior immunity to diphtheria toxin. The results indicated protective levels of antibody were achieved in greater than 90% of the study population after primary immunization with both components. (4)

14.2. Booster Immunization

In a clinical study, the immune response to booster immunization with DECAVAC vaccine was evaluated in 516 adolescents 11-17 years of age and 509 adults 18-64 years of age. Participants had not received a tetanus or diphtheria toxoid-containing vaccine within the previous 5 years. Sera were obtained before and approximately 35 days after vaccination. Antibodies to tetanus toxoid were measured by an ELISA. Antibodies to diphtheria toxin were measured by a microneutralization assay. Seroprotection rates and booster response rates for tetanus are provided in Table 4. Seroprotection rates and booster response rates for diphtheria are provided in Table 5.

Table 4: Pre-vaccination and Post-vaccination Tetanus Seroprotection Rates and Booster Response Rates Following a Booster Dose of DECAVAC Vaccine in Adolescents and Adults 11 Through 64 Years of Age

		Tetanus Antitoxoid (IU/mL)				
		Pre-Vaccination		1 Month Post-Vaccination		
Age Group (years)	N[a]	% ≥0.1[b] (95% CI)	% ≥1.0[c] (95% CI)	% ≥0.1[b] (95% CI)	% ≥1.0[c] (95% CI)	% Booster[d] (95% CI)
11-17	516	99.2 (98.0, 99.8)	43.8 (39.5, 48.2)	100.0 (99.3, 100.0)	99.4 (98.3, 99.9)	91.3 (88.5, 93.6)
18-64	509	95.9 (93.8, 97.4)	70.3 (66.2, 74.3)	99.8 (98.9, 100.0)	98.2 (96.7, 99.2)	66.8 (62.5, 70.9)

[a]N = number of participants in the per-protocol population with available data.

[b]With the ELISA used in this study, a tetanus antitoxoid level of 0.1 IU/mL is considered the protective level.

[c]With the ELISA used in this study, a tetanus antitoxoid level of 1.0 IU/mL is 10 times the protective level.

[d]Booster response is defined as: A four-fold rise in antibody concentration, if the pre-vaccination concentration was equal to or below the cut-off value and a two-fold rise in antibody concentration if the pre-vaccination concentration was above the cut-off value. The cut-off value for tetanus was 2.7 IU/mL.

Table 5: Pre-vaccination and Post-vaccination Diphtheria Seroprotection Rates and Booster Response Rates Following a Booster Dose of DECAVAC Vaccine in Adolescents and Adults 11 Through 64 Years of Age

		Diphtheria Antitoxin (IU/mL)				
		Pre-Vaccination		1 Month Post-Vaccination		
Age Group (years)	N[a]	% ≥0.1[b] (95% CI)	% ≥1.0[c] (95% CI)	% ≥0.1[b] (95% CI)	% ≥1.0[c] (95% CI)	% Booster[d] (95% CI)
11-17	515-516	70.7 (66.5, 74.6)	17.3 (14.1, 20.8)	99.8 (98.9, 100.0)	98.4 (97.0, 99.3)	95.0 (92.7, 96.7)
18-64	506-507	63.3 (59.0, 67.5)	16.0 (12.9, 19.5)	95.1 (92.8, 96.8)	79.9 (76.1, 83.3)	83.4 (79.9, 86.5)

[a]N = number of participants in the per-protocol population with available data.

[b]With the microneutralization assay used in this study, a diphtheria antitoxin level of 0.1 IU/mL is generally regarded as protective.

[c]With the microneutralization assay used in this study, diphtheria antitoxin levels ≥1.0 IU/mL have been associated with long term protection.

[d]Booster response is defined as: A four-fold rise in antibody concentration, if the pre-vaccination concentration was equal to or below the cut-off value and a two-fold rise in antibody concentration if the pre-vaccination concentration was above the cut-off value. The cut-off value for diphtheria was 2.56 IU/mL.

15. REFERENCES

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3 Institute of Medicine (US). Stratton KR, et al, eds. Adverse events associated with childhood vaccines: evidence bearing on causality. Washington (DC): National Academy Press. 1994:67-117.

4 Myers MG, et al. Primary immunization with tetanus and diphtheria toxoids. JAMA 248:1982;2478-2480.

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8 Vitek CR and Wharton M. Diphtheria toxoid. In: Plotkin SA, Orenstein WA, Offit PA, editors. Vaccines. 5th ed. Philadelphia, PA: WB Saunders Company;2008:139-156.

16. HOW SUPPLIED/STORAGE AND HANDLING

16.1. How Supplied

Vial, 1 Dose (10 per package) – NDC 49281-291-83. Contains no latex.

Syringe, 1 Dose (10 per package, without needle) – NDC 49281-291-10. The tip caps of the prefilled syringes may contain natural rubber latex. No other components contain latex.

16.2. Storage and Handling

Store at 2° to 8°C (35° to 46°F). Do not freeze.

Do not use vaccine after expiration date.

17. PATIENT COUNSELING INFORMATION

Prior to administration of DECAVAC vaccine, health-care providers should inform the patient, parent, or guardian of the benefits and risks of immunization and of the importance of completing the primary immunization series or receiving recommended booster doses, as appropriate.

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

The health-care provider should provide the Vaccine Information Statements which are required by the National Childhood Vaccine Injury Act of 1986 to be given with each immunization.

Product information
as of March 2011.

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

5876-5877