PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

Td ADSORBED

Tetanus and Diphtheria Toxoids Adsorbed

Each 0.5 mL dose contains 5 Lf of Tetanus Toxoid and 2 Lf of Diphtheria Toxoid

Suspension for injection

(For active immunization against Tetanus and Diphtheria)

ATC Code: J07AM51

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Td ADSORBED is indicated for active primary and booster immunization for the prevention of tetanus and diphtheria as a single dose in persons 7 years of age and older.

Persons who have had tetanus or diphtheria should still be immunized since these clinical infections do not always confer immunity.

Human Immunodeficiency Virus (HIV)-infected persons, both asymptomatic and symptomatic, should be immunized against tetanus and diphtheria according to standard schedules.

Td ADSORBED is not to be used for the treatment of disease caused by *Corynebacterium diphtheriae* or *Clostridium tetani* infections.

1.1 Pediatrics

Td ADSORBED is not indicated for immunization of children below the age of 7 years.

1.2 Geriatrics

Td ADSORBED is indicated for immunization of persons 7 years of age and older.

Tetanus Prophylaxis in Wound Management

The need for active immunization with a tetanus toxoid-containing preparation such as Td ADSORBED, with or without passive immunization with Tetanus Immune Globulin, depends on both the condition of the wound and the patient's vaccination history. (See 4 DOSAGE AND ADMINISTRATION).

2 CONTRAINDICATIONS

Hypersensitivity

Known systemic hypersensitivity reaction to any component of Td ADSORBED or a life-threatening reaction after previous administration of the vaccine or a vaccine containing one or more of the same components are contraindications to vaccination. (See 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING). Alternatively, such persons may be referred to an allergist for evaluation if further immunizations are considered.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

Primary Immunization

For primary immunization of persons 7 years of age and older, a series of three (0.5 mL) doses is required. The first two doses should be given 4 to 8 weeks apart and the third dose 6 to 12 months later.

Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with Td ADSORBED. There is no need to start the series over, regardless of the time elapsed between doses.

Booster Immunization

For booster immunization of persons 7 years of age and older a single (0.5 mL) dose is required.

There are currently no data upon which to base a recommendation for the optimal interval for administering subsequent booster doses with Td ADSORBED. For persons who have previously been immunized against tetanus and diphtheria, a dose of 0.5 mL should be administered as a reinforcing dose at approximately 10 year intervals.

Fractional doses (doses <0.5 mL) should not be given. The effect of fractional doses on safety and efficacy has not been determined.

Health-care professionals should refer to the NACI guidelines for tetanus prophylaxis in routine wound management shown in Table 1.

Table 1: NACI Recommended Use of Immunizing Agents in Wound Management

History of Tetanus Immunization	Clean, Minor Wounds		All Other Wounds	
	Td*	TIG† (Human)	Td	TIG (Human)
Uncertain or <3 doses of an immunization series**	Yes	No	Yes	Yes
≥3 doses received in an immunization series**	No‡	No	No§	No††

* Adult-type tetanus and diphtheria toxoid.
† Tetanus immune globulin, given at a separate site from the Td.
** Primary immunization is at least 3 doses at age appropriate intervals.
‡ Yes, if >10 years since last booster.
§ Yes, if >5 years since last booster.
†† Yes, if persons are known to have a significant humoral immune deficiency state (e.g., HIV, agammaglobulinemia) since immune response to tetanus toxoid may be suboptimal.

A thorough attempt must be made to determine whether a patient has completed primary immunization. Persons who have completed primary immunization against tetanus and who sustain wounds that are minor and uncontaminated should receive a booster dose of a tetanus toxoid-containing preparation if they have not received tetanus toxoid within the preceding 10 years. For tetanus-prone wounds (e.g., wounds contaminated with dirt, feces, soil and saliva, puncture wounds, avulsions and wounds resulting from missiles, crushing, burns or frostbite), a booster is appropriate if the patient has not received a tetanus toxoid-containing preparation within the preceding 5 years.

4.4 Administration

Administration Route Related Precautions: Do not administer Td ADSORBED by intravascular injection; ensure that the needle does not penetrate a blood vessel.

Intradermal or subcutaneous routes of administration are not to be utilized.

Td ADSORBED should not be administered into the buttocks.

Inspect for extraneous particulate matter and/or discolouration before use (See 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING). If these conditions exist, the product should not be administered.

Shake the vial well until a uniform, cloudy, suspension results. Cleanse the vial stopper with a suitable germicide prior to withdrawing the dose. Do not remove either the stopper or the metal seal holding it in place. Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit for each individual recipient, to prevent disease transmission. Needles should not be recapped but should be disposed of according to biohazard waste guidelines. (See 7 WARNINGS AND PRECAUTIONS).

Before injection, the skin over the site to be injected should be cleansed with a suitable germicide. Administer the total volume of 0.5 mL **intramuscularly** (IM). The preferred site of injection is the deltoid muscle.

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

5 OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 2: **Dosage Forms, Strengths, Composition and Packaging**

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Each single dose (0.5 mL) contains: **Active Ingredients:** Tetanus Toxoid: 5 Lf Diphtheria Toxoid: 2 Lf	**Td Adsorbed with 2-phenoxyethanol (not as a preservative):** 2-phenoxyethanol, Aluminum Phosphate (adjuvant), Isotonic solution of Sodium Chloride in water for injection Manufacturing process residuals: formaldehyde is present in trace amounts
		Td Adsorbed without 2-phenoxyethanol: Aluminum Phosphate (adjuvant), saline, water for injection Manufacturing process residuals: formaldehyde is present in trace amounts

Description

Td ADSORBED is supplied as a sterile, cloudy, white, uniform suspension in a vial.

Each dose (0.5 mL) is formulated to contain: 5 Lf of Tetanus Toxoid and 2 Lf of Diphtheria Toxoid.

The non-medicinal ingredients are as follows:

Td Adsorbed with 2-phenoxyethanol (not as a preservative): Aluminum Phosphate (adjuvant) (1.5 mg); 2-Phenoxyethanol (0.6% v/v) and Isotonic solution of Sodium Chloride in Water for Injection (q.s. to 0.5 mL). Formaldehyde is present in trace amounts.

Td Adsorbed without 2-phenoxyethanol : Aluminum Phosphate (adjuvant) (1.5 mg); saline 0.9% (q.s. to 0.5 mL) and Water for Injection (q.s. to 0.5 mL). Formaldehyde is present in trace amounts.

Packaging

Td ADSORBED is supplied in 0.5 mL single dose glass vials.

The vials are made of Type 1 glass. The container closure system of Td ADSORBED is free of latex (natural rubber).

Td ADSORBED is available in a package of:

Td ADSORBED with 2-phenoxyethanol (not as a preservative): 5 single dose vials

Td ADSORBED without 2-phenoxyethanol: 10 single dose vials

7 WARNINGS AND PRECAUTIONS

General

Before administration of Td ADSORBED, health-care providers should inform the recipient, the parent or guardian of the recipient of the benefits and risks of immunization, inquire about the recent health status of the recipient, review the recipient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and comply with any local requirements regarding information to be provided to the recipient/guardian before immunization.

It is extremely important that the recipient, parent or guardian be questioned concerning any signs or symptoms of an adverse reaction after a previous dose of vaccine. (See 2 CONTRAINDICATIONS and 8 ADVERSE REACTIONS)

The rates and severity of adverse events in recipients of tetanus toxoid are influenced by the number of prior doses and level of pre-existing antitoxins.

Syncope can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling, and injury, and to manage syncope.

As with any vaccine Td ADSORBED may not protect 100% of vaccinated persons.

Febrile and Acute Disease: Vaccination should be postponed in cases of an acute or febrile disease. However, a disease with low-grade fever should not usually be a reason to postpone vaccination.

Hematologic

Because any intramuscular injection can cause an injection site hematoma in persons with any bleeding disorders, such as hemophilia or thrombocytopenia, or in persons on anticoagulant therapy, intramuscular injections with Td ADSORBED should not be administered to such persons unless the potential benefits outweigh the risks of administration. If the decision is made to administer any product by intramuscular injection to such persons, it should be given with caution, with steps taken to avoid the risk of hematoma formation following injection.

Immune

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated. Hypersensitivity reactions may occur following the use of Td ADSORBED even in persons with no prior history of hypersensitivity to the product components. (See 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).

As with all other products, epinephrine hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. Health-care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management. For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

Immunocompromised persons (whether from disease or treatment) may not achieve the expected immune response. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment. Nevertheless, vaccination of persons with chronic immunodeficiency such as HIV infection is recommended even if the immune response might be limited.

Neurologic

A review by the US Institute of Medicine (IOM) found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome (GBS). If GBS occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give Td ADSORBED or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks.

A few cases of demyelinating diseases of the central nervous system, peripheral mononeuropathies and cranial mononeuropathies have been reported following vaccines containing tetanus and/or diphtheria toxoids, although the IOM concluded that the evidence is inadequate to accept or reject a causal relation between these conditions and vaccination.

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction and fertility studies have not been conducted with Td ADSORBED. It is also not known whether Td ADSORBED can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Td ADSORBED should be given to a pregnant woman only if clearly needed, as per national recommendations.

7.1.2 Breast-feeding

It is not known whether the active substances included in Td ADSORBED are excreted in human milk. The effect of administration of Td ADSORBED during lactation has not been assessed. As Td ADSORBED is inactivated, any risk to the mother or the infant is improbable. However, the risks and benefits of vaccination should be assessed before making the decision to immunize a nursing woman.

8 ADVERSE REACTIONS

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

During clinical trials, the most common adverse reactions associated with the administration of Td ADSORBED were pain, swelling and redness at the injection site in all age groups and following both primary and booster immunization.

In a clinical study of primary immunization conducted in Canada, Td ADSORBED was administered as a three dose primary series to 18 subjects, 8 of whom were 6 - 9 years of age and 10 of whom were 17 - 56 years of age. In three booster immunization studies conducted in Canada, Td ADSORBED was administered to 773 subjects overall, ranging in age from 12 - 59 years.

In two of the booster immunization studies, one dose of Td ADSORBED was administered to subjects who were presumed to have previously received primary immunization against tetanus and diphtheria, and had not received tetanus or diphtheria toxoid within 5 years prior to enrollment. The results from these studies are presented in Table 3.

No serious adverse events were reported following vaccination with Td ADSORBED in these studies.

Table 3: Frequencies of Selected Solicited Adverse Events within 72 Hours Following a Dose of Td ADSORBED in Presumably Previously Primed Subjects.

Event	TC9704		TD9707
	Adolescents* N = 37 (%)	Adults N = 263 (%)	Adults N = 126 (%)
Injection Site Reactions			
Redness	5.4	8.4	21.4
Swelling	16.2	13.3	10.3
Pain	81.1	84.8	84.9
Systemic Reactions			
Fever (≥38.0°C)	2.7	4.2	0.8
Chills	8.1	4.6	5.6
Sore or Swollen Joints	8.1	5.3	5.6

* ages 12 – 17 years

8.5 Post-Market Adverse Reactions

The following additional adverse events have been spontaneously reported during the post-marketing use of Td ADSORBED or a similar vaccine manufactured by Sanofi Pasteur, one of identical antigenic content but with thimerosal instead of 2-phenoxyethanol, one of identical tetanus antigen content but lower diphtheria antigen content and thimerosal instead of 2-phenoxyethanol. 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. Decisions to include these events in labelling were based on one or more of the following factors: 1) severity of the event, 2) frequency of reporting, or 3) strength of causal connection to Td ADSORBED.

Blood and Lymphatic System Disorders

Lymphadenopathy

Immune System Disorders

Allergic reactions including anaphylaxis/anaphylactic reactions, urticaria and oedema of the mouth

Nervous System Disorders

Paresthesia, dizziness, syncope

Guillain Barré syndrome (GBS) has been exceptionally reported

Respiratory, Thoracic and Mediastinal disorders

Bronchospasm

Gastrointestinal Disorders

Vomiting

Skin and Subcutaneous Tissue Disorders

Rash, pruritus, rash erythematous, rash maculopapular

Musculoskeletal, Connective Tissue and Bone Disorders

Myalgia, pain in extremities

General Disorders and Administration Site Conditions

Injection site reactions (including inflammation, mass, oedema, induration, warmth, pruritus, cellulitis, discomfort)

Fatigue, oedema peripheral

Physicians, nurses and pharmacists should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements (See PATIENT MEDICATION INFORMATION, Reporting Side Effects for Vaccines).

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Vaccine Drug Interactions
Immunosuppressive treatments may interfere with the development of the expected immune response. (See 7 WARNINGS AND PRECAUTIONS)

Concomitant Vaccine Administration
There are no data available on the concomitant administration of Td ADSORBED with other live or inactivated parenteral vaccines. Vaccine administered simultaneously should be given using separate syringes at separate sites, as appropriate for the recipient's age and previous vaccination status.

The vaccine must not be mixed with other medicinal products.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Tetanus and Diphtheria

Tetanus is an acute and often fatal disease caused by an extremely potent neurotoxin produced by *C. tetani*. The toxin causes neuromuscular dysfunction, with rigidity and spasms of skeletal muscles. Protection against disease attributable to *C. tetani* is due to the development of neutralizing antibodies to tetanus toxin. A serum tetanus antitoxin level of at least 0.01 IU/mL, measured by neutralization assay, is considered the minimum protective level. A tetanus antitoxin level of at least 0.1 IU/mL as

measured by the ELISA used in clinical studies of Td ADSORBED is considered as protective for tetanus. Levels of 1.0 IU/mL have been associated with long-term protection.

Strains of *C. diphtheriae* that produce diphtheria toxin can cause severe or fatal illness characterized by membranous inflammation of the upper respiratory tract and toxin-induced damage to the myocardium and nervous system. Protection against disease attributable to *C. diphtheriae* 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. Antitoxin levels of at least 0.1 IU/mL are generally regarded as protective. Levels of 1.0 IU/mL have been associated with long-term protection.

11 STORAGE, STABILITY AND DISPOSAL

Store at 2° to 8°C (35° to 46°F). **Do not freeze**. Discard product if exposed to freezing.

12 SPECIAL HANDLING INSTRUCTIONS

Do not use after expiration date.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Tetanus Toxoids and Diphtheria Toxoids, Vaccine Adsorbed

Product Characteristics:

Td ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed] is a sterile, cloudy, white uniform suspension of tetanus and diphtheria toxoids adsorbed separately on aluminum phosphate and suspended in isotonic sodium chloride solution for Td Adsorbed with 2-phenoxyethanol (not as a preservative) and suspended in saline for Td Adsorbed without 2-phenoxyethanol.

C. diphtheriae is grown in modified Mueller's growth medium. After purification by ammonium sulphate fractionation, diphtheria toxin is detoxified with formaldehyde and diafiltered. *C. tetani* is grown in modified Mueller-Miller casamino acid medium without beef heart infusion. Tetanus toxin is detoxified with formaldehyde and purified by ammonium sulphate fractionation and diafiltration. Diphtheria and tetanus toxoids are individually adsorbed onto aluminum phosphate.

Td Adsorbed with 2-phenoxyethanol (not as a preservative): The adsorbed diphtheria, tetanus components are combined with aluminum phosphate (as adjuvant), 2-phenoxyethanol (as excipient) and water for injection.

Td Adsorbed without 2-phenoxyethanol : The adsorbed diphtheria, tetanus components are combined with aluminum phosphate (as adjuvant), saline and water for injection.

The potency of tetanus and diphtheria toxoids are measured by *in vitro* antigenicity enzyme-linked immunosorbent assays (ELISA), which detects immunologically relevant epitopes. Alternatively, the potency can be assessed in guinea pigs, with the tetanus toxoid inducing at least 2 neutralizing units/mL of serum and the diphtheria toxoid inducing at least 0.5 neutralizing units/mL of serum

14 CLINICAL TRIALS

14.1 Clinical Trial Design by Indication

Prevention Of Tetanus And Diphtheria As A Single Dose In Persons 7 Years Of Age And Older.

Three clinical trials (TC9704, TD9707 and Primary Immunization Study), conducted in Canada, provide the clinical basis for the licensure of Td ADSORBED in Canada.

Table 4: Summary of Demographics and Study Design of the Trials with Td ADSORBED

Study	Study Design	Dosage and Route of Administration	Study Population* (N = ITT†)	Mean Age (Range)	Gender
TC9704	Randomized, controlled, double-blind, multicentre comparative trial with Td used as control.	0.5 mL I.M.	Adolescents (N = 37) Adults (N = 263)	33.5 years (12.0 - 53.9)	Males (N =95) Females (N =(205)
TD9707	Randomized, controlled, single-blind, multicentre comparative trial with Td used as control.	**0.5 mL I.M.**	Adults (N = 126)	37.93 years (19.43 - 58.48)	Males (N = 44) Females (N = 82)
Primary Immunization study	Open label, single center trial	**0.5 mL I.M.**	Children (N=8) Adults (N=9)	18.75 years (7 - 30.5)	Males (N=5) Females (N=12)

* All studies required participants to be in good health and not have been vaccina
ted against diphtheria, or tetanus within the last 5 years.
† Intent-to-Treat (ITT) population includes all participants who were randomized and received Td ADSORBED.

The efficacy of tetanus toxoid and diphtheria toxoid used in Td ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed] was determined on the basis of immunogenicity studies.

Study Results

Safety

Booster Immunization Studies TC9704 and TD9707

In two of the booster immunization studies conducted in Canada, one dose of Td ADSORBED was administered to participants who were presumed to have previously received primary immunization against tetanus and diphtheria and had not received tetanus or diphtheria toxoid within 5 years prior to enrollment. In both studies, telephone questionnaires to inquire about adverse events were administered at approximately 24 hours, 72 hours, and 14 days following vaccination. Information on adverse events that occurred after 14 days was collected at a subsequent visit, approximately one-month following vaccination. Some study sites distributed worksheets to participants to assist in recording adverse events, although the use and content of worksheets were not standardized. Frequencies of selected solicited adverse events reported anytime during the first 72 hours following vaccination are presented in Table 5. One participant in Study TD9707 reported swelling of the entire injected upper limb. No serious adverse events were reported following vaccination with TD ADSORBED in these studies.

Table 5: Frequencies of Selected Solicited Adverse Events Within 72 Hours Following a Dose of Td Adsorbed in Presumably Previously Primed Subjects

Event	TC9704		TD9707
	Adolescents* ***12 to 17 years old*** **N = 37**	**Adults** ***18 to 54 years old*** **N = 263**	**Adults** ***19-59 years old*** **N = 126**
	%	**%**	**%**
Local			
Redness			
Any	5.4	8.4	21.4
≥35 mm	2.7	1.5	3.2
≥50 mm	2.7	1.1	0.0
≥100 mm	0.0	0.4	0.0
Swelling			
Any	16.2	13.3	10.3
≥35 mm	13.5	5.7	7.1
≥50 mm	10.8	3.8	4.0
≥100 mm	2.7	1.5	0.8
Pain			
Any	81.1	84.8	84.9
Moderate† or worse	18.9	12.2	15.1
Severe‡	0.0	0.4	0.8
Systemic			
Fever			
≥38.0 ºC	2.7	4.2	0.8
≥38.3ºC	0.0	0.0	0.0
Chills	8.1	4.6	5.6
Sore or Swollen Joints	8.1	5.3	5.6

* Ages 12 - 17 years.
† Moderate - interfered with activities but did not require medical care or absenteeism.
‡ Severe - incapacitating, unable to perform usual activities, required medical care or absenteeism.

No serious adverse events were reported following vaccination with Td ADSORBED in these studies.

14.3 Immunogenicity

Serological correlates of protection have been defined for diphtheria and tetanus. The efficacy of the tetanus toxoid and diphtheria toxoid used in Td ADSORBED was inferred by the demonstration that the immune responses to these antigens attain levels previously established as protective (≥0.1 IU/mL).

A serum diphtheria antitoxin level of 0.01 IU/mL is the lowest level giving some degree of protection. Antitoxin levels of ≥0.1 IU/mL are generally regarded as protective. Levels of 1.0 IU/mL have been associated with long-term protection.

A serum tetanus antitoxin in level of ≥0.01 IU/mL measured by neutralization assay is considered the minimum protective level. A tetanus antitoxin level ≥0.1 IU/mL as measured by the ELISA used in clinical studies of Td ADSORBED is considered protective.

Primary Immunization

Primary immunization with tetanus toxoid and diphtheria toxoid used in Td ADSORBED, administered as a series of three doses of Td was evaluated in 17 participants ages 6 to 56 years in a study conducted in Canada. 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. 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.

Booster Immunization

In two studies conducted in Canada (TC9704 and TD9707), the immune responses to a dose of Td ADSORBED were evaluated in subjects who were presumed to have previously received primary immunization against tetanus and diphtheria, and had not received tetanus or diphtheria toxoid within 5 years prior to enrollment. Prior to vaccination and 28 - 35 days following vaccination, serum tetanus antitoxin levels were measured by an ELISA that has been shown to correlate with an *in vivo* neutralizing assay, and serum diphtheria antitoxin levels were measured by an *in vitro* neutralizing assay. The results from these studies are presented in Table 6 and Table 7.

Table 6: Tetanus Antitoxin Levels and Booster Response Rates in Presumably Previously Primed Adolescents and Adults Who Received a Dose of Td ADSORBED

Study / Age Group	Timing*	Percent of Subjects with Specified Levels of Antitoxin and a Booster Response							
		≥0.01 IU/mL		≥0.1 IU/mL		≥1.0 IU/mL		Booster Response†	
		%	95% CI	%	95% CI	%	95% CI	%	95% CI
TC9704									
Adolescents‡ (N = 37)	**Pre-**	97.3	(85.8, 99.9)	89.2	(74.6, 97.0)	10.8	(3.0, 25.4)	-	-
	Post -	100	(90.5, 100)	100	(90.5, 100)	100	(90.5, 100)	100	(90.5, 100)
Adults (N = 263)	**Pre-**	98.9	(96.7, 99.8)	95.1	(91.7, 97.3)	54.4	(48.1, 60.5)	-	-
	Post-	100	(98.6, 100)	99.6	(97.9, 100)	98.9	(96.7, 99.8)	80.6	(75.3, 85.2)
TD9707									
Adults (N = 122)	**Pre-**	99.2	(95.5, 100)	92.6	(86.5, 96.6)	59.0	(49.7, 67.8)	-	-
	Post-	100	(97.0, 100)	100	(97.0, 100)	96.7	(91.8, 99.1)	81.2	(73.1, 87.7)

* Pre: indicates pre-vaccination.
Post: indicates 28 - 35 days post-vaccination.

† Booster response: ≥4-fold increase in post-vaccination antitoxin level relative to pre-vaccination level and post-vaccination level ≥0.1 IU/mL.

‡ Adolescents ages 12 - 17 years.

Table 7: Diphtheria Antitoxin Levels and Booster Response Rates in Presumably Previously Primed Adolescents and Adults Who Received a Dose of Td ADSORBED

Study / Age Group	Timing*	Percent of Subjects with Specified Levels of Antitoxin and a Booster Response					
		≥0.01 IU/mL		≥0.1 IU/mL		Booster Response†	
		%	95% CI	%	95% CI	%	95% CI
TC9704							
Adolescents‡ (N = 37)	**Pre-**	89.2	(74.6, 97.)	56.8	(39.5, 72.9)	-	-
	Post -	100	(90.5, 100)	100	(90.5, 100)	100	(90.5, 100)
Adults (N = 263)	**Pre-**	78.7	(73.3, 83.5)	38.4	(32.5, 44.6)	-	-
	Post-	98.9	(96.7, 99.8)	84.8	(79.9, 88.9)	77.6	(72.0, 82.5)
TD9707							
Adults (N = 122)	**Pre-**	82.8	(74.9, 89.0)	35.2	(26.8, 44.4)	-	-
	Post-	98.4	(94.2, 99.8)	89.3	(82.5, 94.2)	83.6	(75.8, 89.7)

* Pre: indicates pre-vaccination.
Post: indicates 28 – 35 days post-vaccination.

† Booster response: ≥4-fold increase in post-vaccination antitoxin level relative to pre-vaccination level and post-vaccination level ≥0.1 IU/mL.
‡ Adolescents ages 12 - 17 years.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Data in animals revealed no unexpected findings and no target organ toxicity.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Td ADSORBED

Tetanus and Diphtheria Toxoids Adsorbed

Read this carefully before you start taking Td ADSORBED. This leaflet is a summary and will not tell you everything about this product. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Td ADSORBED.

What is Td ADSORBED used for?

Td ADSORBED is a vaccine that is used to boost the body's protection against tetanus and diphtheria. This vaccine may be given to persons 7 years of age and older.

The majority of persons who are vaccinated with Td ADSORBED will produce enough antibodies to protect them against these diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

How does Td ADSORBED work?

Td ADSORBED causes your body to produce its own natural protection against tetanus and diphtheria. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with one of the germs that cause these diseases, the body is usually ready to destroy it.

What are the ingredients in Td ADSORBED?

Each 0.5 mL dose of Td ADSORBED contains:

Medicinal ingredients: tetanus toxoid and diphtheria toxoid.

Non-medicinal ingredients:

Td Adsorbed with 2-phenoxyethanol (not as a preservative):
Aluminum phosphate, 2-phenoxyethanol, isotonic solution of sodium chloride in water for injection. Residual formaldehyde is present in trace amounts.

Td Adsorbed without 2-phenoxyethanol :
Aluminum phosphate, saline and water for injection. Residual formaldehyde is present in trace amounts.

Td ADSORBED comes in the following dosage forms:

Td ADSORBED is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not use Td ADSORBED if:

- persons who are known to have a severe allergy to any ingredient in the vaccine or its container, or who have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Td ADSORBED. Talk about any health conditions or problems you may have including:

- **A high fever or serious illness**. Delay the vaccination until the person is better.
- **An allergy to any component of the vaccine or the container.**
- **A serious nervous system adverse event following a previous tetanus vaccination.**
- **Pregnant or nursing mothers.** It is important that you understand the risks and benefits of vaccination. Td ADSORBED should be given to a pregnant woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **A weakened immune system**. The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system.
- **A bleeding disorder or taking blood-thinning medications**. Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.
- **Fainting can occur following, or even before, any needle injection. Therefore, tell your doctor or nurse if your child fainted with a previous injection.**

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Td ADSORBED:

- DO NOT mix Td ADSORBED with other vaccines or medicinal products in the same syringe.

How to take Td ADSORBED :

Usual dose:

Td ADSORBED may be used for primary and booster vaccination.

The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region.

Primary Immunization

A series of three (0.5 mL) doses is required for the primary immunization of persons 7 years of age and older. The first two doses should be given 4 to 8 weeks apart and the third dose 6 to 12 months later.

A delay between doses should not interfere with the final immunity achieved with Td ADSORBED. There is no need to start the series over, regardless of the time elapsed between doses.

Booster Immunization

A single (0.5 mL) dose is required for booster immunization of persons 7 years of age and older.

For persons who have previously been immunized against tetanus and diphtheria, a dose of 0.5 mL should be administered as a reinforcing dose at approximately 10 year intervals.

Overdose:

If you think you, or a person you are caring for, have taken too much Td ADSORBED, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable for this vaccine.

What are possible side effects from using Td ADSORBED?

These are not all the possible side effects you may have when taking Td ADSORBED. If you experience any side effects not listed here, tell your healthcare professional.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of Td ADSORBED causing serious harm is extremely small. The small risks associated with Td ADSORBED are much less than the risks associated with getting the diseases.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving Td ADSORBED.

Serious side effects are extremely rare.

Some people who receive Td ADSORBED may have mild side effects such as pain, swelling and redness at the injection site. These side effects usually go away within a few days.

Serious side effects and what to do about them		
Symptom / effect	**Talk to your healthcare professional**	
	Only if severe	**In all cases**
Allergic reactions including Anaphylaxis/Anaphylactic reactions urticaria and oedema of the mouth		✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php) and send it to your local Health Unit.

Storage:

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Throw the product away if it has been exposed to freezing.

Do not use after the expiration date.

Keep out of reach and sight of children.

If you want more information about Td ADSORBED:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the Sanofi Canada website (https://www.sanofi.com/en/canada) or by calling the vaccine producer at 1-888-621-1146 (no charge).

This leaflet was prepared by Sanofi Pasteur Limited.

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