PRODUCT MONOGRAPH

Td POLIO ADSORBED

Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine

Suspension for Injection

(For Active Immunization Against
Tetanus, Diphtheria and Poliomyelitis)

ATC Code: J07CA01

Manufactured by:

Sanofi Pasteur Limited

Toronto, Ontario, Canada

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular injection	Suspension for injection. Each dose (0.5 mL) is formulated to contain: 5 Lf tetanus toxoid 2 Lf diphtheria toxoid purified inactivated poliomyelitis vaccine Type 1 (Mahoney) 40 D-antigen units Type 2 (MEF1) 8 D-antigen units Type 3 (Saukett) 32 D-antigen units	2-phenoxyethanol aluminum phosphate formaldehyde polysorbate 80 bovine serum albumin trace amounts of neomycin and polymyxin B *For a complete listing see Dosage Forms, Composition and Packaging section.*

DESCRIPTION

Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine] produced by Sanofi Pasteur Limited, is a sterile, cloudy, white, uniform suspension of tetanus and diphtheria toxoids adsorbed on aluminum phosphate and suspended in phosphate buffered saline solution and combined with Inactivated Poliomyelitis Vaccine for intramuscular injection only.

INDICATIONS AND CLINICAL USE

Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine] is indicated for active immunization of persons 7 years of age and older

for prevention of tetanus, diphtheria and poliomyelitis. Td POLIO ADSORBED may be used for primary immunization and for boosters.

Persons who have had tetanus or diphtheria should still be immunized since these clinical infections do not always confer immunity. (1) Persons who have had poliomyelitis may receive IPV, as they may not be fully protected against all 3 poliovirus serotypes.

HIV-infected individuals, both asymptomatic and symptomatic, should be immunized against tetanus, diphtheria and poliomyelitis according to standard schedules. (1)

Tetanus

Tetanus is an acute and often fatal disease caused by an extremely potent neurotoxin produced by *Clostridium tetani.* The organism is ubiquitous and its occurrence in nature cannot be controlled. Immunization is highly effective, provides long-lasting protection and is recommended for the whole population. Only 1 to 7 cases of tetanus were reported annually in Canada during the 1990s. (1)

Neonatal tetanus occurs among infants born under unhygienic conditions to inadequately vaccinated mothers. Vaccinated mothers confer protection to their infants through transplacental transfer of maternal antibody. (2)

Diphtheria

Diphtheria is a serious communicable disease caused by toxigenic strains of *Corynebacterium diphtheriae*. The organism may be harboured in the nasopharynx, skin or other sites of asymptomatic carriers, making eradication of the disease difficult. Routine immunization against diphtheria in infancy and childhood has been widely practiced in Canada since 1930. Fewer than 2 cases are now reported annually in Canada. The case-fatality rate remains at 5 to 10%, with the highest death rates in the very young and elderly. The disease occurs most frequently in unimmunized or partially immunized persons.

Poliomyelitis

Poliomyelitis is a disease that may cause irreversible paralysis in a certain proportion of infected individuals. It is a highly infectious disease caused by three types of the enterovirus poliovirus. (1) It is primarily spread by the fecal-oral route of transmission but may also be spread by the pharyngeal route. Following introduction of poliovirus vaccines in Canada in 1955, the indigenous disease has been virtually eliminated. However, circulation of wild viruses does occur in rare circumstances, (3) and it remains crucial that the highest possible level of vaccine-induced immunity be maintained in the population.

Pediatrics

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

CONTRAINDICATIONS

Known systemic hypersensitivity to any component of Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine], after previous administration of the vaccine, or after a vaccine containing the same substances is a contraindication to vaccination. (See components listed in DOSAGE FORMS, COMPOSITION AND PACKAGING.)

Immunization with Td POLIO ADSORBED should be deferred in the presence of any acute illness, including febrile illness to avoid superimposing adverse effects from the vaccine on the underlying illness or mistakenly identifying a manifestation of the underlying illness as a complication of vaccine use. A minor illness such as mild upper respiratory infection is not a reason to defer immunization. (1) The National Advisory Committee on Immunization (NACI) has published guidelines for vaccination of persons with recent acute illness.

WARNINGS AND PRECAUTIONS

General

Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine] should not be administered into the buttocks due to the varying amount of fatty tissue in this region, nor by the intradermal route, since these methods of administration may induce a weaker immune response.

As with any vaccine, immunization with Td POLIO ADSORBED may not protect 100% of susceptible individuals.

Do not inject into a blood vessel.

Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual dose to prevent disease transmission.

Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization, and current health status.

Before administration of Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine], health-care providers should inform the patient, parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunization and the importance of completing the immunization series.

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

Hematologic

Because of the risk of bleeding and hematoma formation following an intramuscular injection, Td POLIO ADSORBED should be given with caution in persons with any bleeding disorder, such as hemophilia or thrombocytopenia, or to persons on anticoagulant therapy. (1)

Immune

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. (1) For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated.

Immunocompromised persons (whether from disease or treatment) may not obtain the expected immune response. (1) If possible, consideration should be given to delaying routine vaccination until after the completion of any immunosuppressive treatment. (1)

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. (4) If Guillain-Barré Syndrome occurred within 6 weeks of immunization with a previous dose of vaccine containing tetanus toxoid, the decision to give subsequent doses of Td POLIO ADSORBED or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. (5)

Special Populations

Pregnant Women

There is no experience with Td POLIO ADSORBED in clinical trials in pregnant women. Animal reproduction studies have not been conducted with Td POLIO ADSORBED. It is also not known whether Td POLIO ADSORBED can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

NACI states that there is no evidence that tetanus toxoid is teratogenic, but it is prudent to wait until the second trimester of pregnancy to administer a routinely required dose, to minimize concern about the theoretic possibility of a relationship with any observed birth defect. In the event of a tetanus-prone wound during pregnancy the recommendations in Table 2 should be followed. (1)

Nursing Women

The effect of administration of Td POLIO ADSORBED during lactation has not been assessed.

NACI states that lactating mothers who have not received the recommended immunizations may safely be given vaccines. (1)

ADVERSE REACTIONS

In a clinical trial involving 40 individuals previously immunized against tetanus, diphtheria and poliomyelitis who received a single (0.5 mL) injection of Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine], the vaccinees experienced only a low level of reactions associated with the injections. Discomfort at the injection site was usually of short duration. Systemic complaints included headache, malaise and dizziness. No fever was reported. (6)

The percent of vaccinees reporting local and general reactions on the day of immunization (day 0) and for the following 3 days are shown in Table 1. Except for muscle aches at the injection site, all reactions were mild or moderate in severity.

Table 1: Frequencies of Selected Solicited Adverse Events Within 72 Hours Following a Dose of Td Polio Adsorbed in Presumably Previously Primed Subjects (N = 40) (6)

Reaction	Percent Reactivity			
	Time Post Injection			
Local	Day 0	Day 1	Day 2	Day 3
Redness	3	3	3	3
Tenderness	38	43	0	0
Induration	3	5	3	0
Swelling	3	3	3	0
Pain	25	33	10	0
Itchiness	5	3	0	0
Muscle Ache, All (severe)	55 (3)	55 (3)	0	0
Systemic				
Headache	8	5	8	0
Dizziness	0	3	0	0
Malaise	3	3	0	0

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.

Post-Market Spontaneous Adverse Drug Reactions

The adverse events reported during the commercial use of Td POLIO ADSORBED are presented below. Because these 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 most commonly reported adverse drug reactions were injection site reactions and pyrexia, both described in 29% of the spontaneous adverse event reports.

Data are organized by MedDRA system organ class and within the system organ class, by decreasing frequency.

Immune system disorders

Allergic reactions (including urticaria, pruritus, rash)

Nervous system disorders

Dizziness, paraesthesia, headache. Guillain-Barré syndrome has been exceptionally reported

Musculoskeletal, connective tissue and bone disorders

Arthralgia, myalgia

General disorders and administration site conditions

Injection site reactions (including injection site inflammation, injection site mass, injection site pain, injection site pruritus); pyrexia; asthenic conditions: fatigue, asthenia, malaise

Additional Adverse Drug Reactions

Additional adverse reactions have been reported following immunization with vaccines containing tetanus toxoid and/or diphtheria toxoid.

Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2-8 hours after an injection), may follow immunization with tetanus toxoid. Such reactions may be associated with high levels of circulating antitoxin in persons who have had overly frequent injections of tetanus toxoid. (4)

Persistent nodules at the site of injection have been reported following the use of adsorbed products. (2)

Cases of allergic or anaphylactic reaction (i.e., hives, swelling of the mouth, difficulty breathing, hypotension, or shock) have been reported after receiving some preparations containing diphtheria and/or tetanus toxoid. (2) Death following vaccine-caused anaphylaxis has been reported. (4)

Certain neurological conditions have been reported in temporal association with some tetanus toxoid-containing vaccines or tetanus and diphtheria toxoid-containing vaccines. A review by the US Institute of Medicine (IOM) concluded that the evidence favours acceptance of a causal relation between tetanus toxoid and both brachial neuritis and Guillian-Barré syndrome. Other neurological conditions that have been reported include: demyelinating diseases of the central nervous system, peripheral mononeuropathies, cranial mononeuropathies, and EEG disturbances with encephalopathy (with or without permanent intellectual and/or motor function impairment). The IOM has concluded that the evidence is inadequate to accept or reject a causal relation between these conditions and vaccines containing tetanus and/or diphtheria toxoids. In the differential diagnosis of polyradiculoneuropathies following administration of a vaccine containing tetanus toxoid, tetanus toxoid should be considered as a possible etiology. (4)

Physicians, nurses, and pharmacists should report any adverse occurrences temporally associated with the administration of the product in accordance with local requirements and to the Global Pharmacovigilance Department, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, ON, M2R 3T4, Canada. 1-888-621-1146 (phone) or 416-667-2435 (fax).

DRUG INTERACTIONS

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. (See WARNINGS AND PRECAUTIONS – Immune.)

Administering the most widely used live and inactivated vaccines during the same patient visit has produced seroconversion rates and rates of adverse reactions similar to those observed when the vaccines are administered separately. (1) (5) Simultaneous administration using separate syringes at separate sites is suggested, particularly when there is concern that an individual may not return for subsequent vaccination. (1)

DOSAGE AND ADMINISTRATION

Booster

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

For individuals planning to travel to developing countries where safe tetanus toxoid administration may not be available if required, it may be prudent to offer an early tetanus toxoid-containing booster prior to travel if more than 5 years have elapsed since the last dose. (1)

Primary Immunization

For primary immunization of persons aged 7 years and older a series of three (0.5 mL) doses is required. The first two doses should be given 2 months apart and the third dose 6 - 12 months later. Thereafter booster doses are recommended at approximately 10 year intervals. (1) (2) NACI states that the first 2 doses should be given 4 - 8 weeks apart.

Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine]. There is no need to start the series over again, regardless of the time elapsed between doses.

Diphtheria Prophylaxis for Case Contacts

NACI has published recommendations on vaccination for diphtheria prophylaxis in persons who have had contact with a person with confirmed or suspected diphtheria. (1)

Tetanus Prophylaxis in Wound Management

The following Table summarizes the recommended use of immunizing agents in wound management. It is important to ascertain the number of doses of tetanus toxoid previously given and the interval since the last dose. If not clearly documented, a history of immunization should be regarded as "uncertain". When a tetanus booster is required the combined preparation formulated for adults containing 5 Lf of tetanus toxoid and 2 Lf of diphtheria toxoid per 0.5 mL dose is preferable (i.e., Td POLIO ADSORBED). (1) Appropriate cleansing and debridement of the wound is imperative.

Some persons with humoral immune deficiency, including those with HIV infection, may not respond adequately to tetanus toxoid. Therefore, tetanus immune globulin (TIG) should be used in addition to tetanus toxoid if a wound occurs that is not clean, regardless of the time elapsed since the last booster. (1)

Table 2: Summary Guide to Tetanus Prophylaxis in Routine Wound Management for Persons 7 Years of age or Older (1)

History of Adsorbed Tetanus Toxoid (Doses)	Clean, Minor Wounds		All Other Wounds	
	Td*	TIG†	Td*	TIG
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 toxoids-containing vaccine (for 7 years and older) such as Td Polio Adsorbed. If the patient is <7 years old, an appropriate tetanus combination vaccine such as QUADRACEL® or PENTACEL® is given.

† Tetanus immune globulin, given at a separate site from Td POLIO with separate syringe.

‡ Primary immunization is at least 3 doses at age appropriate intervals.

§ Yes, if >10 years since last booster.

** Yes, unless there is documentation of a booster within the last 5 years.

†† Yes, if individuals are known to have a significant humoral immune deficiency state (e.g., HIV, agammaglobulinemia) since immune response to tetanus toxoid may be suboptimal.

Administration

Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.

SHAKE THE VIAL WELL to uniformly distribute the suspension before withdrawing each dose. When administering a dose from a stoppered vial, 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 dose to prevent disease transmission. (See WARNINGS AND PRECAUTIONS.)

Administer the vaccine **intramuscularly**. The preferred site is into the deltoid muscle. Do not inject intravenously.

Needles should not be recapped and should be disposed of according to biohazard waste guidelines.

For information on vaccine administration see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

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.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

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. (5) (7) (8) 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 for both tetanus and diphtheria. (5) (8) Levels of 1.0 IU/mL have been associated with long-term protection. (8)

Poliomyelitis is caused by poliovirus Types 1, 2 or 3. Inactivated poliomyelitis vaccine induces the production of detectable levels of neutralizing antibodies against each type of poliovirus. The detection of type-specific neutralizing antibodies has been correlated with protection. (9) A primary series induces protective antibody levels in more than 99% of recipients.

Pharmacokinetics

Not applicable.

Duration of Effect

After completion of a primary series, circulating antibodies to tetanus and diphtheria toxoids gradually decline but are thought to persist at protective levels for up to 10 years. Tetanus and diphtheria boosters are recommended every 10 years.

STORAGE AND STABILITY

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

Do not use after expiration date.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

The stopper of the vial for this product does not contain dry natural latex rubber.

Vials 5 x 0.5 mL (Single Dose)

Composition

Each dose (0.5 mL) is formulated to contain:

tetanus toxoid	5 Lf
diphtheria toxoid	2 Lf
purified inactivated poliomyelitis vaccine	
Type 1 (Mahoney)	40 D-antigen units
Type 2 (MEF1)	8 D-antigen units
Type 3 (Saukett)	32 D-antigen units

Other ingredients per dose include 0.5% v/v of 2-phenoxyethanol (not as a preservative), 1.5 mg of aluminum phosphate equivalent to 0.33 mg of aluminum as the adjuvant, and 27 ppm of formaldehyde.

The vaccine also contains approximately 10 ppm polysorbate 80 and ≤50 ng of bovine serum albumin (by calculation). Trace amounts of neomycin and polymyxin B may be present from the cell growth medium.

Vaccine Information Service: 1-888-621-1146 or 416-667-2779

Visit us at www.sanofipasteur.ca

Full product monograph available on request.

Product information as of December 2010
Manufactured by:

Sanofi Pasteur Limited

Toronto, Ontario, Canada

R11-1210 Canada

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine

Product Characteristics

Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine] produced by Sanofi Pasteur Limited, is a sterile, cloudy, white, uniform suspension of tetanus and diphtheria toxoids adsorbed on aluminum phosphate and suspended in phosphate buffered saline solution and combined with Inactivated Poliomyelitis Vaccine for intramuscular injection only.

Clostridium tetani is grown in modified Mueller-Miller casamino acid medium without beef heart infusion. (10) Tetanus toxin is detoxified with formaldehyde and purified by ammonium sulphate fractionation and diafiltration. *Corynebacterium diphtheriae* is grown in modified Mueller's growth medium. (11) After purification by ammonium sulphate fractionation, diphtheria toxin is detoxified with formaldehyde and diafiltered. Tetanus and diphtheria toxoids are individually adsorbed onto aluminium phosphate.

Inactivated Poliomyelitis Vaccine is a sterile suspension of three types of poliovirus: Type 1 (Mahoney), Type 2 (MEF1) and Type 3 (Saukett). The viruses are grown in cultures of MRC-5 cells, a line of normal human diploid cells, by the microcarrier technique. The cells are grown in CMRL 1969 medium supplemented with calf serum. For viral growth the culture medium is replaced by M-199, without calf serum. After clarification and filtration, viral suspensions are concentrated by ultrafiltration and purified. The monovalent viral suspensions are inactivated with formaldehyde. Monovalent concentrates of each type are then combined to produce a trivalent concentrate.

CLINICAL TRIALS

The safety and immunogenicity of Td POLIO ADSORBED [Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine] was demonstrated in clinical trials in adolescents (12) and adults who had received previous immunization against tetanus, diphtheria and poliomyelitis.

Study Demographics and Trial Design

Table 3: Summary of Patient Demographics for Clinical Trials - Booster

Study #	Trial Design	Dosage, Route of Administration	Study Subjects (n=number)	Age (Range)	Gender
Study 1 (6)	Open	0.5 mL IM	40	(26-53)	M21 F19

Study Results

The efficacy of tetanus toxoid, diphtheria toxoid and inactivated poliomyelitis vaccine used in Td POLIO ADSORBED was determined on the basis of immunogenicity studies, with a comparison to a serological correlate of protection.

In a clinical trial involving 40 individuals previously immunized against tetanus, diphtheria and poliomyelitis, a single (0.5 mL) injection of Td POLIO ADSORBED, stimulated a prompt antibody response to each of the antigens - tetanus, diphtheria and poliovirus types 1, 2, and 3. (6) Twenty eight days after immunization, 100% of vaccinees had tetanus antitoxin levels of ≥0.08 IU/mL, diphtheria antitoxin levels of ≥0.01 IU/mL and poliovirus antibody type 1 titres of ≥1:512, type 2 titres of ≥1:1024 and type 3 titres of ≥1:2048.

Table 4: Antibody Titres in Recipients of a Single (0.5 mL) Injection of Td Polio Adsorbed

	Pre-injection (n = 40)	**28 Days Post Injection (n = 38)**
	G.M.T.*	**G.M.T.***
Tetanus Antitoxin IU/mL	0.202	1.277
Diphtheria Antitoxin IU/mL	0.089	0.991
Poliovirus Neutralizing Antibody		
Type 1	630	2950
Type 2	653	10968
Type 3	431	44681

* G.M.T. = Geometric Mean Titre

Primary Immunization

The immunogenicity of the tetanus and diphtheria components of Td POLIO ADSORBED administered as a series of three (0.5 mL) injections for primary immunization has been demonstrated in a small number (17) of individuals whose ages ranged from 6 to 56 years. These individuals were all confirmed unimmunized to both tetanus and diphtheria. Four weeks following the second injection of vaccine, given two months after the first, all had responded with serum tetanus antitoxin levels ranging from 0.11 to 14.0 IU/mL and with diphtheria antitoxin levels ranging from 0.01 to 1.28 IU/mL. Following the third injection of vaccine 6 to 8 months after second, the 8 individuals tested developed antitoxin titres to tetanus of 0.56 to 14.0 IU/mL and to diphtheria of 0.16 to 5.12 IU/mL. (6)

Inclusion of inactivated poliomyelitis vaccine with the tetanus and diphtheria toxoids adsorbed and the spacing of the three injections at 0, 2 and 6-12 months, produced an adequate neutralizing antibody response to all three types of poliovirus. (6)

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Vaccine Information Service: 1-888-621-1146 or 416-667-2779

Visit us at www.sanofipasteur.ca

Full product monograph available on request.

Product information as of December 2010

Manufactured by:

Sanofi Pasteur Limited

Toronto, Ontario, Canada

R11-1210 Canada

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Td POLIO ADSORBED

Tetanus and Diphtheria Toxoids Adsorbed and Inactivated Poliomyelitis Vaccine

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Td POLIO ADSORBED. Contact your doctor, nurse or pharmacist if you have any questions about the vaccine.

ABOUT THIS MEDICATION

What the medication is used for:

Td POLIO ADSORBED is a vaccine that is used to provide protection against tetanus, diphtheria and poliomyelitis disease. This vaccine may be given to persons 7 years of age or older.

Tetanus, also known as lockjaw, is a deadly disease that develops very quickly. Tetanus is caused by an extremely strong nerve poison produced by the germ *Clostridium tetani*. This germ is present everywhere in nature. It usually gets into the body through a dirty wound or cut. **Diphtheria** is a serious contagious disease caused by the germ *Corynebacterium diphtheriae*. This germ may be carried in the nose, throat and on the skin of persons who show no signs of being sick. **Poliomyelitis** is a highly contagious infectious disease caused by three types of poliovirus. The poliovirus is a virus most recognized for its destruction to the nervous system causing paralysis. It is primarily spread by the fecal-oral route.

The majority of people who are vaccinated with Td POLIO ADSORBED will produce enough antibodies to protect them against all 3 diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

What it does:

Td POLIO ADSORBED causes your body to produce its own natural protection against tetanus toxin, diphtheria toxin and polio viruses. After you get a Td POLIO ADSORBED injection, your body begins to make substances called antibodies. Antibodies help your body to fight disease.

When you are exposed to tetanus or diphtheria bacteria or polio viruses, the antibodies will help to keep you from getting sick.

When it should not be used:

Td POLIO ADSORBED should not be used in the following situations:

- Do not give Td POLIO ADSORBED to anyone who has had an allergic reaction to any component of the vaccine or its container.
- Do not give Td POLIO ADSORBED to a person who has a fever or serious illness. Wait until the person is better before giving the vaccine. A person who has had a mild illness (such as a mild cold) may have the vaccine. Ask your doctor, nurse or pharmacist for advice.

What the medicinal ingredient is:

Each 0.5 mL dose of Td POLIO ADSORBED contains: tetanus toxoid, diphtheria toxoid and purified inactivated poliomyelitis vaccine.

What the important nonmedicinal ingredients are:

Aluminum phosphate

Formaldehyde

2-phenoxyethanol

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

A liquid vaccine dose of 0.5 mL for intramuscular injection.

WARNINGS AND PRECAUTIONS

If you or your child has any of the following conditions, talk to your doctor, nurse or pharmacist BEFORE you receive Td POLIO ADSORBED:

- **Persons with diseases of the immune system or taking a medical treatment that affects the immune system**. The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **A serious nervous system adverse event (Guillain-Barré syndrome or brachial neuritis) following a dose of vaccine containing tetanus toxoid.**

- **Persons who have bleeding disorders or are on blood-thinning medications.** Tell the person giving you the injection about your condition. There is a risk of excessive bleeding where you get the injection if it is not done carefully.
- **Pregnant or breast-feeding women.** It is important that you understand the risks and benefits of vaccination. Td POLIO ADSORBED should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Td POLIO ADSORBED must not be mixed with other vaccines or medicinal products in the same syringe.

PROPER USE OF THIS MEDICATION

Usual dose:

For persons 7 years of age and older, the recommended dose is 0.5 mL. The vaccine should be given in the muscle, preferably in the deltoid (shoulder) region.

People who have not received at least 3 doses of any tetanus, diphtheria and polio vaccines during their lifetime should do so using Td POLIO ADSORBED. After a person gets the third dose, a Td booster dose is needed every 10 years all through life. It may be needed after 5 years if you have a dirty wound. People travelling to areas of the world where polio is common may need a polio vaccine booster. This could be in the form of a Td POLIO booster.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If a dose is missed, it can be given at any time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

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

Serious side effects are extremely rare.

Some people who receive Td POLIO ADSORBED may have mild side effects such as redness, swelling or pain at injection site. They may also feel unwell, have a headache or dizziness. These side effects may last a day or two.

This is not a complete list of side effects. For any unexpected effects while taking Td POLIO ADSORBED, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze**. Discard product if it has been exposed to freezing.
Do not use after the expiration date.
Keep out of reach of children.

REPORTED SUSPECTED SIDE EFFECTS

To monitor vaccine safety, Health Canada collects information on serious and unexpected effects of vaccine(s). If you suspect you have had a serious or unexpected reaction to this vaccine you may notify Health Canada by:

Telephone: 613-952-6339
Fax: 613-946-0224
By email: VAAES@phac-aspc.gc.ca

By regular mail:
The Vaccine Safety Unit
Immunization & Respiratory Infections Division
Centre for Infectious Disease Prevention & Control
Public Health Agency of Canada
PL 0602C Bldg #6, Tunney's Pasture
Ottawa, Ontario
K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician, nurse or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.sanofipasteur.ca or by contacting the sponsor, Sanofi Pasteur Limited,
1755 Steeles Avenue West, Toronto, Ontario,
M2R 3T4.
Phone: 1-888-621-1146 or 416-667-2779

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