PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

TUBERSOL®

Tuberculin Purified Protein Derivative (Mantoux)

Solution, 5 Tuberculin units (TU) per 0.1 mL test dose, Intradermal injection

Diagnostic Antigen to aid in the detection of infection with *Mycobacterium tuberculosis*

ATC Code: V04CF01

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

TUBERSOL® [Tuberculin Purified Protein Derivative (Mantoux)] is indicated to aid diagnosis of tuberculosis infection (TB) in persons at increased risk of developing active disease. There are three general situations where risk of disease is increased:

- Recent infection – most commonly contacts of a recently diagnosed patient with active contagious pulmonary TB, or immigrants within five years of their arrival in Canada from countries where TB is still common.
- Increased risk of reactivation due to impaired immunity. This includes Human Immunodeficiency Virus (HIV) infection, diabetes, renal failure, corticosteroids or other immuno-suppressant medication and pulmonary silicosis.
- Radiographic evidence of old healed inactive TB but no prior treatment.

Previous BCG vaccination is not a contraindication to tuberculin testing. TUBERSOL® may be used as an aid in the diagnosis of tuberculosis infection in persons with a history of BCG vaccination.

The repeated testing of uninfected persons does not sensitize them to tuberculin.

2 CONTRAINDICATIONS

TUBERSOL® should not be administered to:

- persons with known hypersensitivity to TUBERSOL® or to any components of the formulation or container. (For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING),
- persons who have had a severe reaction (e.g., necrosis, blistering, anaphylactic shock or ulcerations) to a previous tuberculin skin test,
- persons with documented active tuberculosis or a clear history of treatment for TB infection or disease, and
- persons with extensive burns or eczema because of greater likelihood of adverse reactions or severe reactions.

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

The recommended dosage per test is 0.1 mL of TUBERSOL®, comprising 5 tuberculin units (TU).

The Mantoux test is performed by injecting 0.1 mL (5 Tuberculin units per test dose) of TUBERSOL® intradermally, in the volar aspect of the forearm.

TUBERSOL® is a clear colourless liquid. Inspect for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.

4.4 Administration

1. The preferred site of the test is the volar aspect of the forearm. Avoid areas on the skin that are red or swollen. Avoid visible veins.
2. The skin site is first cleansed with a suitable germicide and should be dry prior to injection of the antigen.
3. The test dose (0.1 mL) of TUBERSOL® is administered with a 1 mL syringe calibrated in tenths and fitted with a short, one quarter to one half inch, 26 or 27 gauge needle.
4. The stopper of the vial should be wiped with a suitable germicide and should be dry before needle insertion. The needle is then inserted gently through the stopper and 0.1 mL of TUBERSOL® is drawn into the syringe. Care should be taken to avoid injection of excess air with removal of each dose so as not to over pressurize the vial thus causing possible seepage at the puncture site.
5. The point of the needle is inserted into the most superficial layers of the skin with the needle bevel pointing upward and the dose administered by slow **intradermal** injection. If the intradermal injection is performed properly, a definite pale bleb will rise at the needle point, about 10 mm (3/8") in diameter. This bleb will disperse within minutes. No dressing is required.
6. A drop of blood may appear at the administration site following injection. Blot the site lightly to remove the blood but avoid squeezing out the tuberculin.

In the event of an improperly performed injection (i.e., no bleb formed), the test should be repeated immediately at another site, at least 5 cm (2 inches) from the first site and the second injection site circled as an indication of the site to be read.

Inform the patient of the need to return for the reading of the test by a trained health professional. Self-reading is inaccurate and strongly discouraged.

Interpretation of the Test

The skin test should be read by a trained health professional 48 to 72 hours after administration of TUBERSOL®. Skin test sensitivity is indicated by induration only; redness should not be measured.

The diameter of the induration should be measured transversely to the long axis of the forearm and recorded in millimetres (including 0 mm). The tip of a ballpoint pen pushed at a 45° angle toward the site of injection will stop at the edge of induration. Presence and size of necrosis and edema (if present) should also be recorded, although it is not used in the interpretation of the test.

The significance of induration measurements in diagnosing latent TB infection must be considered in terms of the patient's history and his risk of developing active TB disease as indicated in Table 1 :

Table 1: Interpretation of Test Results, Size of Induration.

TST Reaction Size (mm induration)	Setting in which reaction is considered significant (meaning probable TB infection).
0-4	HIV infection with immune suppression AND the expected likelihood of TB infection is high (e.g., patient is from a population with a high prevalence of TB infection, is a close contact of an active contagious case, or has an abnormal X-ray). This reaction size is not normally considered significant, but in the presence of immune suppression may be important.
5-9	HIV infection Contact of active contagious case Children suspected of having tuberculosis disease Abnormal chest X-ray with fibronodular disease Other immune suppression: TNF-alpha inhibitors, chemotherapy
≥10	All others

The possibility should be considered that skin test sensitivity may also be due to previous contact with atypical mycobacteria or previous BCG vaccination.

The Booster Effect and Two-step Testing

If tuberculin testing will be conducted at regular intervals, for instance among healthcare or prison workers, two-step testing should be performed as a baseline to avoid interpreting a booster effect as a tuberculin conversion. If the first test showed either no reaction or a small reaction, the second test should be performed one to four weeks later. Both tests should be read and recorded at 48 to 72 hours. Patients with a second tuberculin test (booster) response of 10 mm or more should be considered to have experienced past or old infection.

Persons who do not boost when given repeat tests at one week, but whose tuberculin reactions change to positive after one year, should be considered to have newly acquired *M. tuberculosis* infection and managed accordingly.

Give the patient a permanent personal record. In addition, it is essential that the health professional record the testing history in the permanent medical record of each patient. This permanent office record should contain the name of the product, date given, dose, manufacturer and lot number, as well as the test result in millimetres of duration (including 0 mm, if appropriate). Reporting results only as negative or positive is not satisfactory.

5 OVERDOSAGE

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

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 2: Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intradermal Injection	**Dosage Form:** Solution **Active Ingredients:** Five (5) Tuberculin units (TU) per test dose of 0.1 mL. Tuberculin Purified Protein Derivative of *Mycobacterium tuberculosis*	Polysorbate 80 Preservative: Phenol

Description

TUBERSOL® is a clear, colourless liquid.

TUBERSOL® [Tuberculin Purified Protein derivative (Mantoux)] for intradermal tuberculin testing is prepared from a large Master Batch Connaught Tuberculin (CT68) and is a cell-free purified protein fraction obtained from a human strain of *M. tuberculosis* grown on a protein-free synthetic medium and inactivated. The use of a standard preparation from a single batch (CT68) has been adopted in order to eliminate batch to batch variation by the same manufacturer.

Composition

TUBERSOL® contains:

Purified protein derivative of *M. tuberculosis* 5 TU per 0.1 mL

Polysorbate 80 0.0006% (w/v)

Phenol 0.22% to 0.35% (w/v)

in sterile isotonic phosphate buffered saline.

Packaging

TUBERSOL® bioequivalent to 5 US units (TU) PPD-S per test dose (0.1 mL) is available in the following presentations:

Vial – 1 mL (5 TU per 0.1 mL test dose),

Vial – 5 mL (5 TU per 0.1 mL test dose)

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

7 WARNINGS AND PRECAUTIONS

General

Do not inject intravenously or intramuscularly.

Do not inject subcutaneously. If this occurs, the test cannot be interpreted. (See 4 DOSAGE AND ADMINISTRATION section).

Proper use of the tuberculin skin test requires knowledge of the antigen used (tuberculin), the immunological basis for the reaction to this antigen, the technique(s) of administering and reading the test, and the results of epidemiologic and clinical experience with the test.

Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient's history concerning possible hypersensitivity to the product or similar products, previous testing history with TUBERSOL®, the presence of any contraindications to the use of TUBERSOL®, and the patient's current health status.

Use a separate, sterile needle and syringe, or a sterile disposable unit, for each individual recipient, to prevent disease transmission.

Hypersensitivity

Acute allergic reactions, including anaphylaxis, angioedema, urticaria and/or dyspnea, have been very rarely reported following skin testing with TUBERSOL®. Allergic reactions may occur following the use of TUBERSOL® even in persons with no prior history of hypersensitivity to the product components.

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. Healthcare providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management.

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

Monitoring and Laboratory Tests

Limitations in Predictive Value

False Positive Tests

In any population, the likelihood that a positive test represents a true infection is influenced by the prevalence of infection with *M. tuberculosis*. False positive tuberculin reaction tests occur in individuals who have been infected with other mycobacteria, including vaccination with BCG. However, a diagnosis of *M. tuberculosis* infection and the use of preventative therapy should be considered for any BCG-vaccinated person who has a positive tuberculin skin-test reaction, especially if the person has been, or is at, increased risk of acquiring TB infection. (See 4 DOSAGE AND ADMINISTRATION , 4.4 Administration, Interpretation of Test Results, section).

Since tuberculin reactivity may not necessarily indicate the presence of active tuberculosis disease, persons showing a tuberculin reaction should be further evaluated with other diagnostic procedures.

False Negative Tests

Not all persons infected with *M. tuberculosis* will have a delayed hypersensitivity reaction to TUBERSOL®.

There is no age contraindication to tuberculin skin testing of infants. Many infants <6 months of age who are infected with *M. tuberculosis* do not react to tuberculin tests because their immune systems are immature.

In the elderly and individuals who are being tested for the first time, reactions may develop slowly and may not peak until after 72 hours. (See 4 DOSAGE AND ADMINISTRATION , 4.4 Administration, Interpretation of Test Results, section).

Since tuberculin sensitivity may take up to 8 weeks to develop following exposure to *M. tuberculosis* (See 10 CLINICAL PHARMACOLOGY, 10.1 Mechanism of Action section), persons who have a negative tuberculin test immediately following possible exposure should be retested ≥8 weeks following the initial test.

Altered Immune Status

Impaired or attenuated cell mediated immunity (CMI) may cause a false negative tuberculin reaction. A large number of factors have been reported to cause a decreased ability to respond to the tuberculin test in the presence of tuberculosis infection, including viral infections (e.g., measles, mumps, chickenpox and HIV infection [cutaneous anergy associated with progressive HIV-associated immunosuppression]), live virus vaccinations (e.g., mumps, rubella, varicella and yellow fever vaccines), overwhelming tuberculosis, other bacterial infections, fungal infections, metabolic derangements, low protein states, diseases affecting lymphoid organs, immunosuppressive drugs, malignancy and stress.

Tuberculin skin testing should be deferred for patients with major viral infections or patients who have received attenuated live-virus vaccines in the past month. Persons with the common cold may be tuberculin tested.

7.1 Special Populations

7.1.1 Pregnant Women

Animal reproduction studies have not been conducted with TUBERSOL®. However, the Canadian Tuberculosis Standard indicates that women who are pregnant can receive a tuberculin skin test. No teratogenic effects of testing during pregnancy have been documented.

The risk of unrecognized tuberculosis and close postpartum contact between a mother with active disease and an infant leaves the infant in grave danger of tuberculosis and complications such as tuberculosis meningitis. Therefore, the prescribing physician should consider if the potential benefits outweigh the possible risks for performing the tuberculin test on a pregnant woman or a woman of childbearing age, particularly in certain “high risk populations” (see 13 PHARMACEUTICAL INFORMATION, Additional Relevant Information).

7.1.2 Breast-feeding

It is not known whether TUBERSOL® is excreted in human milk. Caution must be exercised when TUBERSOL® is administered to a nursing mother. TUBERSOL® should be administered to nursing mothers only if clearly needed following an assessment of the risks and benefit.

7.1.3 Pediatrics

Due to immature immune systems, many infants <6 months of age who are infected with *M. tuberculosis* do not react to tuberculin tests. Older infants and children develop tuberculin sensitivity 3-6 weeks or more after initial infection.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Induration at the TUBERSOL® injection site is the expected reaction for a positive skin test. (See 4 DOSAGE AND ADMINISTRATION , 4.4 Administration, Interpretation of Test Results, section).

8.5 Post-Market Adverse Reactions

The information pertaining to Adverse Events has been compiled from historical clinical studies and post-marketing experience with TUBERSOL®.

General disorders and administration site conditions

Injection site pain, injection site pruritus, injection site discomfort

Injection site erythema or injection site rash (without induration) occurring within 12 hours of testing. These reactions do not indicate TB infection.

Injection site haemorrhage and injection site haematoma up to three days after the administration of the test have been seen.

Injection site vesicles, injection site ulcer or injection site necrosis may appear at test site in highly sensitive persons.

Injection site scar as a result of strongly positive reactions.

Pyrexia

Immune system disorders

Hypersensitivity, anaphylaxis/anaphylactic reaction, angioedema, urticaria

Respiratory, thoracic and mediastinal disorders

Stridor, dyspnea

Skin and subcutaneous tissue disorders

Rash, generalized rash

Nervous system disorders

Presyncope, syncope

Healthcare professionals 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

Reactivity to the test may be depressed or suppressed in persons who are receiving corticosteroids or immunosuppressive agents.

9.7 Drug-Laboratory Test Interactions

Diagnostic Test – Vaccine Interactions

Vaccination with live attenuated virus can cause suppression of the tuberculin test response in patients known to be infected with *M. tuberculosis*. Reactivity to TUBERSOL® may be temporarily depressed by certain live virus vaccines (measles, mumps, rubella, oral polio, yellow fever, and varicella). When tuberculin screening is required at the same time as a measles-containing vaccine or other parenteral live attenuated virus vaccine, simultaneous administration of TUBERSOL® and the vaccine at separate sites is the preferred option. If the parenteral live attenuated virus vaccine has been administered recently, tuberculin testing should be delayed for >1 month after vaccination.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Intradermal tuberculin testing is an accepted aid in the diagnosis of tuberculosis infection.

The sensitization following infection with mycobacteria occurs primarily in the regional lymph nodes. Small lymphocytes (T lymphocytes) proliferate in response to antigenic stimulus to give rise to specifically sensitized lymphocytes. After 3-8 weeks, these lymphocytes enter the blood stream and circulate for long periods of time. Subsequent restimulation of these sensitized lymphocytes with the same or similar antigen, such as the intradermal injection of tuberculin, evokes a local reaction mediated by these cells.

The reaction to intradermally injected tuberculin is a delayed (cellular) hypersensitivity reaction. The reaction which characteristically shows a delayed course, reaching its peak more than 24 hours after administration, consists of induration due to cell infiltration and occasionally vesiculation and necrosis. Clinically, a delayed hypersensitivity reaction to tuberculin is a manifestation of prior infection with *M. tuberculosis* or a variety of non-tuberculosis bacteria or by vaccination with BCG vaccine.

Immediate hypersensitivity reactions to tuberculin may occur but disappear within 24 hours.

11 STORAGE, STABILITY AND DISPOSAL

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

At no time should TUBERSOL® be exposed to direct or indirect sunlight. Exposure to artificial light should also be kept to a minimum.

A **vial of TUBERSOL® which has been entered and in use for 30 days should be discarded.**

12 SPECIAL HANDLING INSTRUCTIONS

Do not use after expiration date.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Tuberculin Purified Protein Derivative (Mantoux)

Product Characteristics:

TUBERSOL® is a Polysorbate 80 (Tween 80) stabilized solution of PPD (bioequivalent to 5 TU). It is prepared from a Master Batch CT68 obtained from the "Johnston" strain of *Mycobacterium tuberculosis var. hominis* grown on a protein-free synthetic medium (Long's Synthetic Medium).

Independent studies conducted by the U.S Public Health Services in humans have determined the amount of CT68 in stabilized solution necessary to produce bio-equivalency with Tuberculin PPD-S (in phosphate buffer without polysorbate 80) using 5 US units (TU) Tuberculin PPD-S as the standard.

Before release, each successive lot is tested for potency in comparison with a reference standard.

Additional Relevant Information

In Canada, the overall rate of *M. tuberculosis* infection is low, with an incidence rate of approximately 4.7 per 100,000 population in 2013. Due to the low rate of infection, the primary method of continued disease control and reduction focuses on surveillance and screening of high risk populations. Specifically, several groups have been identified as high risk populations within Canada and include; close contacts of individuals with known or suspected active TB, persons with HIV infection, persons with a history of active TB infection, Aboriginal communities with high rates of latent tuberculosis infection (LTBI) or TB, the poor or homeless, staff and residents of long-term care and correctional facilities, persons who face occupational exposure to TB and foreign-born persons referred for medical surveillance by immigration authorities.

The tuberculin skin test is useful in epidemiologic surveys to define the prevalence of infection in population groups or to estimate prevalence or risk of infection in certain population groups.

All healthcare workers (HCWs) (pre-placement and presently employed) should have their TB infection status documented. Ongoing surveillance for TB in HCWs includes both regular ongoing screening and post-exposure screening.

Travellers at high risk of exposure to TB due to travel in a high-endemic environment, who have a medical condition increasing the risk of TB, have "high-risk" lengths of travel (>1 month), or participate in high-risk activities leading to probable exposure should have a pre-exposure tuberculin skin testing (TST). Post-exposure TST, or testing at least every 2 years, should be done for all tuberculin-negative reactors.

14 CLINICAL TRIALS

Data on which indications were initially approved is not available.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Purified tuberculin has been used since 1934 in humans and animals, and its safety is recognized. Tubersol® has been used safely in humans since 1956.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TUBERSOL®

Tuberculin Purified Protein Derivative (Mantoux)

Read this carefully before you start taking TUBERSOL® and each time you receive TUBERSOL®. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about TUBERSOL®.

What is TUBERSOL® used for?

TUBERSOL® is used in a screening test (the tuberculin skin test) to determine if a person has been infected by the bacteria that cause tuberculosis, *Mycobacterium tuberculosis*.

Tuberculosis (TB) is an infectious disease that can affect any part of the body but is most often associated with an infection of the lungs. Not everyone who is infected with TB bacteria will show signs and symptoms of infection.

You are most likely to need this test if you:

a) have been around someone with TB,

b) have a weakened immune system due to certain medications or diseases (e.g., cancer, HIV infection and AIDS),

c) have had abnormal chest x-ray results.

How does TUBERSOL® work?

The tuberculin skin test involves 2 steps and will require 2 visits to your doctor's office. During the first visit, a small amount of TUBERSOL® is injected into the topmost layers of skin on the inner forearm, causing a small bump. TUBERSOL® contains proteins from the TB-causing bacteria, which provoke a localized skin reaction in individuals that have been infected with these bacteria.

It is important that you return to your doctor's office after 48 to 72 hours, where a trained healthcare professional will evaluate if you have had a significant reaction to TUBERSOL®. Self-reading is inaccurate and strongly discouraged.

A positive reaction to the skin test includes a palpable, raised and hardened area at the site where TUBERSOL® was injected.

For some individuals, who are going to be retested periodically, such as healthcare workers or correctional facility staff, a second skin test, after an initial negative skin test is useful (two-step testing). This two-step approach can reduce the likelihood that a boosted reaction to a subsequent TB skin test will be misinterpreted as a recent infection.

A positive reaction to TUBERSOL® may indicate inactive infection, prior infection and/or disease with *M. tuberculosis* and does not necessarily indicate the presence of active tuberculosis disease. Persons showing reactivity to TUBERSOL® should be evaluated by other diagnostic procedures, such as x-ray examination of the chest and microbiological examination of a productive cough.

What are the ingredients in TUBERSOL®?

Medicinal ingredients: Purified protein derivative of *M. tuberculosis.*

Non-medicinal ingredients: Polysorbate 80, Phenol

TUBERSOL® comes in the following dosage forms:

TUBERSOL® is a liquid that is intended for injection into the topmost layers of the skin; (5 Tuberculin Units (TU) per 0.1 mL test dose).

TUBERSOL® should not be given to patients:

- who are known to have a severe allergy to this skin test agent or its container,
- who have had severe reaction (e.g., necrosis, blistering, ulcerations) to a previous tuberculin skin test,
- with documented active tuberculosis or a clear history of treatment for tuberculosis infection or disease,
- with extensive burns or eczema.

If you or your child are being tested and have any of the following conditions, talk to your doctor or nurse healthcare professional BEFORE being tested with TUBERSOL®.

- Severe allergy to a previous tuberculin test.
- A weakened immune system due to drugs that suppress your immune system or due to a recent illness.
- Recent vaccination with a live viral vaccine, such as MMR (measles, mumps and rubella) vaccine.

A false positive test can occur in persons who have been vaccinated with the BCG vaccine or who have been infected with non-tuberculosis mycobacteria.

A false negative test can occur if the body's immune system is immature (in infants) or impaired, due to infections or immunosuppressive drugs.

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 TUBERSOL®:

Live virus vaccines (e.g., measles and chickenpox vaccines) may interfere with reactivity to TUBERSOL®. For people scheduled to receive a tuberculin skin test, testing should be done either on the same day as vaccination or at least one month after administration of the live virus vaccine.

Drugs that suppress the immune system (e.g., corticosteroids) may interfere with reactivity to TUBERSOL®. If possible, try to postpone the tuberculin skin test until after you have completed the treatment that affects your immune system.

How to take TUBERSOL®:

Usual dose:

For each tuberculin skin test, 0.1 mL (5 TU) test dose of TUBERSOL® is injected under the top layer of skin of the forearm.

Testing Instructions

The result of the TUBERSOL® skin test must be read by a trained health professional 48 to 72 hours following administration. Self-reading is inaccurate and strongly discouraged.

Overdose:

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

What are possible side effects from using TUBERSOL®?

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

TUBERSOL® may cause serious problems, such as severe allergic reactions. Tell your doctor or nurse as soon as possible if you do not feel well after the tuberculin skin test has been administered.

Some people who receive TUBERSOL® may experience side effects such as redness, itching, bruising or pain at the site of TUBERSOL® injection. Rarely, rashes or shortness of breath have also been reported. These side effects usually go away within a few days.

If you believe that you are experiencing an allergic reaction following TUBERSOL® administration, notify a healthcare professional immediately.

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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 2° to 8°C. **Do not freeze.** The product should be stored in the dark except when doses are being withdrawn from the vial.

Keep out of reach and sight of children.

If you want more information about TUBERSOL®:

- 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 (www.sanofi.ca) or by contacting the manufacturer, Sanofi Pasteur Limited at 1- 888-621-1146.

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