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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