

21/12/2021

טוברסול / Tubersol
solution for injection
Tuberculin purified protein 5 TU/ 0.1 mL

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,
חברת מדיצי' מדיקל בע"מ מודיעה על עדכון העלון לרופא. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה.
עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (החמרה מסומנת ברקע צהוב). מחיקות לעומת
גרסה קודמת מסומנות כפ. ותוספות מסומנות כב.

ההתוויה הרשומה לתכשיר בישראל:

An aid in the detection of infection with mycobacterium tuberculosis

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

[...]

DESCRIPTION

[...]

Before release, each successive lot is tested for potency in comparison with ~~the US Standard Tuberculin PPD-S~~ a reference standard.

[...]

Interpretation of the Test

[...]

Positive Reactions

Tuberculin reactivity may indicate latent infection, prior infection and/or disease with *M. tuberculosis* and does not necessarily indicate the presence of active tuberculous disease. Persons showing positive tuberculin reactions should be considered positive by current public health guidelines and referred for further medical evaluation. The repeated testing of uninfected persons does not sensitize them to TUBERSOL.

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

Table 1: Interpretation of Test Results, Size of Induration.
Table 1: Criteria for tuberculin positivity, by risk group

<p>TST Reaction Size (<u>≥5 mm induration</u>)<u>of Induration</u></p>	<p>Setting in which reaction is considered significant (meaning probable TB infection):<u>Reaction ≥ 10 mm of Induration</u></p>	<p>Reaction ≥ 15 mm of Induration</p>
<p><u>HIV-positive persons</u></p> <p><u>Recent contacts of tuberculosis (TB) case patients</u></p> <p><u>Fibrotic changes on chest radiograph consistent with prior TB</u></p> <p><u>Patients with organ transplants and other immunosuppressed patients (receiving the equivalent of ≥ 15 mg/d of prednisone for 1 month or more)*</u></p>	<p>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.<u>Recent immigrants (i.e., within the last 5 yrs) from high prevalence countries</u></p> <p><u>Injection drug users</u></p> <p><u>Residents or employees† of the following high-risk congregate settings: prisons and jails, nursing homes and other long-term facilities for the elderly, hospitals and other healthcare facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS) and homeless shelters</u></p> <p><u>Mycobacteriology laboratory personnel</u></p> <p><u>Persons with the following clinical conditions that place them at high risk: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of $\geq 10\%$ of ideal body weight, gastrectomy and jejunioileal bypass</u></p> <p><u>Children younger than 4 yrs of age or infants, children, and adolescents exposed to adults at high-risk</u></p>	<p>Persons with no risk factors for TB</p>
<p>5-9</p>	<p>HIV infection</p> <p>Contact of active contagious case</p> <p>Children suspected of having tuberculosis disease</p> <p>Abnormal chest X ray with fibronodular disease</p> <p>Other immune suppression: TNF alpha inhibitors, chemotherapy</p>	
<p>≥ 10</p>	<p>All others</p>	

* Risk of TB in patients treated with corticosteroids increases with higher dose and longer duration.

† For persons who are otherwise at low risk and are tested at the start of employment, a reaction of ≥ 15 mm induration is considered positive.

A TST conversion is defined as an increase of ≥ 10 mm of induration within a 2-year period, regardless of age.

[...]

False Positive Reactions

False positive tuberculin reactions can 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 preventive therapy should be considered for any BCG-vaccinated person who has a positive TST reaction, especially if the person has been, or is, at increased risk of acquiring TB infection.

~~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 Reactions

Not all infected persons will have a delayed hypersensitivity reaction to a tuberculin test.

In those who are elderly or those who are being tested for the first time, reactions may develop slowly and may not peak until after 72 hours.

Since tuberculin sensitivity may take up to 8 weeks to develop following exposure to *M. tuberculosis* (see **Mechanism of Action**), persons who have a negative tuberculin test immediately < 8 weeks following possible TB exposure should be retested $\geq 8-10$ weeks following the initial test, last known or suspected exposure.

[...]

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן. העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: <https://data.health.gov.il/drugs/index.html#!/byDrug>

וניתן לקבלו מודפס על ידי פניה לבעל הרישום מדיצי' מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון 09-7446170

בברכה,

ירון חסיד,
רוקח ממונה