

1. NAME OF THE MEDICINAL PRODUCT

PPD Tuberculin Mammalian, 5TU/ 0.1 ml, solution for intradermal injection
Tuberculin Purified Protein Derivative

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

The preparation is a cell-free purified protein fraction obtained from a human strain of *M. tuberculosis*, grown on a protein-free synthetic medium and inactivated at temperature.

The preparation is a sterile isotonic solution of PPD Tuberculin in phosphate buffered saline, containing Tween 80 (0.005%) as stabilizer and phenol (up to 0.25%) as antimicrobial preservative.

Potency is expressed in Tuberculin Units (TU) bio-equivalent to International Units of the International Standard (PPD-S) per test dose (0.1 ml) (9; 33).

The product meets the WHO Requirements for Tuberculins (TRS 745) and European Pharmacopoeia: 0151.

PPD Tuberculin Mammalian 5 TU/0.1 ml - 1 dose contains:

	Component	Quantity
Active ingredient	Tuberculin Purified Protein Derivative	5 TU*
Other ingredients	Tween 80 as stabilizer	5.0 µg
	Phenol as preservative	≤ 0.25 mg
	Isotonic phosphate buffer	pH – 6.5-7.5
	- disodium hydrogen phosphate R	0.76 mg
	- potassium dihydrogen phosphate R	0.145 mg
- sodium chloride R	0.48 mg	
	Water for injection	q.s. 0,1 ml

* Bio-equivalent to 5 IU of Tuberculin PPD-S (9, 33)

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3. PHARMACEUTICAL FORM

PPD Tuberculin is an injectable solution ready for intradermal application (I.D.), without dilution.

Clear colourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications:

One single human dose for I.D. application is 0.1 ml

Standard clinical dose is 5 TU/0.1 ml.

PPD Tuberculin solutions are ready to use for Mantoux's intradermal test to assist in clinical diagnosis of tuberculosis for :

- diagnosis and differential diagnosis of tuberculosis;
- early detection of tuberculosis in children;
- screening for infection by M.tuberculosis or atypical mycobacteria;
- examination for allergy acquired after BCG vaccination;
- identification of subjects for BCG revaccination (7).
- HIV-infected individuals should receive tuberculin skin testing as recommended (3; 26; 30; 32).

4.2. Posology and method of administration

The Mantoux test is performed by injection intradermally, with a syringe and needle, 0.1ml of PPD Tuberculin. For the intradermal (Mantoux) tuberculin test, **the standard dose is 5 TU in 0.1ml.**

Appointing and reading the skin tuberculin reaction and its interpretation is complete from a medical doctor.

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Method of Administration:

1. The site of the test is the flexor surface of the forearm dorsal or volar site, distant from blood vessels.
2. The skin of the forearm is first cleansed with alcohol and allowed to dry.
3. The test dose (0.1 ml) of PPD Tuberculin is administered with a 1 ml syringe calibrated in tenths and fitted with a short, one-half inch 26 or 27 gauge needle.
4. Disposable sterile syringes and needles may be used.
5. Wipe the rubber cap of the vial with an alcohol swab. The needle is then inserted gently through the cap and 0.1 ml of PPD Tuberculin is drawn into the syringe.
6. The point of the needle is inserted into the most superficial layers of the skin with the needle bevel pointing upward. If the intradermal injection is performed properly, a definite pale bleb will rise at the needle point, about 10 mm in diameter. This will disappear within minutes.
7. A separate sterile syringe and needle must be used for each individual injection to prevent the possibility of transmission of viral hepatitis or other infectious agents from one person to another. In particular, the same needle and/or syringe must never be used to re-enter a multi-dose vial to withdraw product even when it is to be used for testing of the same patient. This may lead to contamination of the vial contents and infection of patient who subsequently receive product from the vial.

In the event of an improperly performed injection (i.e. no bleb formed), **the test should be repeated immediately at another site.**

Interpretation of the Test:

The test should be read 72 hours after administration of the tuberculin. Sensitivity is indicated **by induration only**; redness should not be measured. **The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimetres (mm).** Presence of oedema or necrosis should also be recorded, although it is not used in the interpretation of the test.

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How to read the Mantoux Test		
Diameter of induration in millimetre		
Negative	Positive	Strongly positive
0 – < 5 mm	≥ 5 – 15 mm	> 15 mm

A positive reaction indicates a response of the immune system due to one or more of the following reasons:

- Infection with Mycobacterium tuberculosis complex (*M. tuberculosis*, *M. bovis*, *M. africanum* or *M. microti*)

- Infection with non-tuberculous mycobacteria.

- Previous BCG vaccination (BCG vaccinated persons normally become tuberculin positive after 4 – 8 weeks). Postvaccinal allergy is usually with sizes of about 6 – 13 mm. The skin reaction is pale with smoothly outlines and hasn't infectious aspect. Postvaccinal allergy gradually diminished.

In countries where is take the BCG vaccination, children respond with negative reaction (induration of less than 5 mm) to the usual tuberculin test (5 TU/0.1 ml) are reimmunized with BCG vaccine, according to National immunization programme.

- Reactions with a diameter larger than 15 mm are defined as strongly positive and give a strong indication of infection with Mycobacterium tuberculosis complex.

Those individuals giving a positive tuberculin reaction may or may not show evidence of tuberculosis disease. Chest x-ray examination and microbiological examination of the sputum in these cases are recommended as a means of determining the presence or absence of pulmonary tuberculosis.

BCG vaccination may produce a PPD reaction that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*. For a person who was vaccinated with BCG, the probability that a PPD reaction results from infection with *M. tuberculosis* increases a) as the size of the reaction increases, b) when the person is

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a contact of a person with TB, c) when the person's country of origin has a high prevalence of TB, and d) as the length of time between vaccination and PPD testing increases (2, 4).

For example, a PPD test reaction of 10 mm probably can be attributed to *M. tuberculosis* infection in an adult who was vaccinated with BCG as a child and who is from a country with high prevalence of TB.

False-Negative Reactions

False-negative tuberculin skin-test reactions have many potential causes (6; 11; 22).

- **Anergy** – When a person's immune system is weakened by a disease such as HIV, cancer or even severe tuberculosis itself, the body may not be able to react to the tuberculin skin test (3; 24).
- **Recent tuberculous infection** – If a person has been infected with the past ten weeks, the tuberculin Mantoux test can not detect a tuberculous infection.
- **Age** – Babies less than 6 months old may have false negative Mantoux test results because their immune system is not fully developed yet.
- **Test administration** - A false result may occur if the tuberculin skin test is not administered correctly.

Booster Effect

The “Booster Phenomenon” in Purified Protein Derivative (PPD) tuberculosis testing occurs when a person's immune system has “forgotten” about an infection by *Mycobacterium tuberculosis* until years later when the person is tested again for tuberculosis; the PPD test “reminds” the immune system about the infection.

Although the initial PPD test was negative, a second PPD test performed year later, may “boost” the immune system's ability to react to the tuberculin. Therefore, there is no way of knowing if the positive result was due to the booster phenomenon.

The best way to avoid this from happening is **to perform a two step test.**

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The two-step tuberculin test involves a person getting re-tested one week after the initial Mantoux test. If both tuberculin tests are negative, the person is unlikely to have tuberculosis. Furthermore, if a future tuberculosis test is positive, it can be concluded that the tuberculosis infection is new and not due to the tuberculosis “booster phenomenon” (29).

4.3. Contraindications:

Known hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings and precautions for use

Effective use of tuberculin testing requires an understanding of the characteristics inherent to the test and extrinsic factors relating that have influence on interpretation of the results. The utility of the tuberculin test depends:

- ◆ on the prevalence of infection with *M. tuberculosis* and the relative prevalence of cross-reaction with non-tuberculosis mycobacteria.(6; 28).

- ◆ Vaccination with BCG vaccine.

A separate, **sterile** syringe and needle, or a sterile disposable unit, must be used for each patient to prevent the transmission of infectious agents from one person to another.

Needles should be recapped and should be disposed of according to applicable biohazard waste guidelines.

Special care should be taken to ensure the product is given intradermally and on the dorsal or volar aspect of the forearm.

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

Do not inject intravenously or intramuscularly.

Do not inject subcutaneously. If this occurs, the test cannot be interpreted !

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Carcinogenesis, Mutagenesis, Impairment of Fertility

Tuberculin PPD has not been evaluated for its carcinogenic or mutagenic potentials or impairment of fertility (26; 31).

The product should not be used for extended treatment over a long period of time.

HIV – infected persons

Because in HIV-infected individuals, tuberculin skin-test results are less reliable as CD4 counts decline, screening should be completed as early as possible after HIV-infection occurs. Those HIV-infected patients at high risk for continuing exposure to patients who have TB should be screened periodically for TB infection. If they have TB symptoms or if they are exposed to a patient who has pulmonary TB, HIV-infected persons should be evaluated promptly for TB. Because active disease can develop rapidly in HIV-infected persons, the highest priority for contact investigation should be given to persons potentially co infected with HIV and TB (3; 8; 24; 30; 32).

Information for Patients

The health-care provider should instruct patients to report to the health-care provider adverse events such as vesiculation, ulceration or necrosis which may appear at the test site in highly sensitive patients.

The health-care provider should also inform the patient that pain, pruritus and discomfort at the site may also occur.

The health-care provider should inform the patient of the need to return for the reading of the test. Self reading of the test has been shown to be unreliable.

The health-care provider should inform the patient of the need to maintain a personal immunization record.

Laboratory Tests

Tuberculin reactivity may indicate prior infection and/or disease with *M. tuberculosis* and does not necessarily indicate the presence of active tuberculous disease.

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Individuals showing tuberculin reactions considered positive by current public health guidelines should be evaluated by other diagnostic procedures, such as x-ray examination of the chest and microbiological examination of the sputum and other modern laboratory tests.

4.5. Interaction with other medicinal products and other forms of interaction

Reactivity to the test may be depressed or suppressed for up to 6 weeks in individuals who have had viral infections (rubella, influenza, mumps and probably others) or in those who are receiving corticosteroids or immunosuppressive agents. Reactivity to PPD may be temporarily depressed by certain live virus vaccines (measles, mumps, rubella, oral polio, yellow fever, and varicella (5; 22). Therefore, if a tuberculin test is to be performed it should be administered either before, or simultaneously at separate sites with the injection of measles, mumps and rubella vaccines, in combined form or as separate antigens, or testing should be postponed for 4-6 weeks.

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

Pediatric use - There is no age contraindication to tuberculin skin testing of infants. Because their immune systems are immature, many infants < 6 weeks of age who are infected with *M. tuberculosis* do not react to tuberculin tests. Older infants and children develop tuberculin sensitivity 6 weeks or more after initial infection.

4.6. Pregnancy and lactation

Pregnancy Category C (Tuberculin)

Well- conducted epidemiological studies indicate no adverse effects of PPD Tuberculin on pregnancy or on the health of the foetus/new-born child. (11; 20; 31)
PPD Tuberculin can be used during pregnancy.

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

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4.8. Undesirable effects

Common (> 1/100)	Local: Pain, irritation or discomfort at the injection site immediately after the injection.
Uncommon (< 1/100)	Systematic: Headache, fever. Local: Enlargement of regional lymph node.
Rare (< 1/ 1.000)	Local: Hypersensitivity to tuberculin can cause vesiculation and skin necrosis. Systematic: Anaphylactic reactions.

4.9. Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): V 04 CF 01.

Pharmacological class: A. 30. 1. Biological antigen.

Scheduling Status: S2

5.2. Pharmacokinetic properties

Tuberculin PPD is indicated for the detection of a delayed hypersensitivity reaction to tuberculin as an aid in the detection of infection with *Mycobacterium tuberculosis*.

Clinically, a delayed hypersensitivity reaction to tuberculin is a manifestation of:

- Previous infection with *M. tuberculosis* or non-tuberculosis bacteria.
- Sensitization by previous vaccination with BCG Vaccine.

The reaction to intradermally injected tuberculin is a delayed (cellular) hypersensitivity reaction. The tuberculin reaction is characterized by the early predominance of mononuclear cells (small and medium sized lymphocytes and monocytes). Only a small proportion of these cells appear to be lymphocytes sensitized to tuberculin. Most cells are brought into the reaction through the release of

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biologically active substances by sensitized lymphocytes. An increase in vascular permeability leading to erythema and edema also occurs in tuberculin reactions.

Characteristically, delayed hypersensitivity reactions to tuberculin begin at 5 to 6 hours, are maximal at 48 to 72 hours and subside over a period of days.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

	Component	Quantity
Excipients	Tween 80 as stabilizer	5.0 µg
	Phenol as preservative	≤ 0.25 mg
	Isotonic phosphate buffer	pH – 6.5-7.5
	- disodium hydrogen phosphate R	0.76 mg
	- potassium dihydrogen phosphate R	0.145 mg
- sodium chloride R	0.48 mg	
	Water for injection q.s.	0,1 ml

6.2. Incompatibilities

This medical product must not be mixed with other medical products.

6.3. Shelf life

2 years from the last satisfactory Potency test.

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Multi-dose vials of Tuberculin PPD from which one or more doses have been removed, may be used for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. (36). WHO/V&B/00.09:

- The expiry date has not passed;
- The Tuberculin PPD is stored under appropriate cold chain conditions (in the dark at temperature $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$);
- The product vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses;

6.4. Special precaution for storage

Tuberculin PPD should be stored between $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.

DO NOT FREEZE. Discard product if exposed to freezing.

Tuberculin solutions can be adversely affected by exposure to light (16).

The product should be stored in the dark.

Once opened, multi-dose vials should be kept between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$.

Do not use after the expiry date.

6.5. Nature and contents of container

Type I glass vials (14)

0,2 ml (2 doses) containing 10 TU of PPD = 5 TU/0.1 ml

1 ml (10 doses) containing 50 TU of PPD = 5 TU/0.1 ml

1,5 ml (15 doses) containing 75 TU of PPD = 5 TU/0.1 ml

2 ml (20 doses) containing 100 TU of PPD = 5 TU/0.1 ml

Tuberculin PPD solutions do not require future dilution.

6.6. Special precaution for disposal

No special requirements.

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7. MARKETING AUTHORISATION HOLDER

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Tel.: **359 2 9446 191,

Fax: 359-2-9433455,

e-mail: bulbio@bulbio.com

8. MARKETING AUTHORISATION NUMBER

No. II – 11522/13.12.2010

Reg. No. 20000719 /19.11.2000

ATC-V04CF01

**9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE
AUTHORISATION**

First registration in Bulgaria – 1977.

Date of last registration in Bulgaria: 19 November 2000

Date of last renewal: 13 December 2010

10. DATE OF REVISION OF THE TEXT

September 2013

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**PPD Tuberculin Mammalian
Leaflet**

**PPD TUBERCULIN Mammalian
(TUBERCULIN PURIFIED PROTEIN DERIVATIVE)
Solution injection for Intradermal**

COMPOSITION:

Tuberculin PPD for human use 1 dose – 5 TU / 0.1 ml contains:

Tuberculin Purified Protein Derivative	5 TU *
Tween 80 as stabilizer	5.0 µg
Phenol as preservative	≤ 0.25 mg
Isotonic phosphate buffer	pH – 6.5-7.5
Disodium hydrogen phosphate	0.76 mg
Potassium dihydrogen phosphate	0.145 mg
Sodium chloride	0.48 mg
Water for injection	q.s. 0.1 ml

* Bio-equivalent to 5 IU of PPD-S (International Standard) per test dose (0.1 ml)

The product meets WHO requirements for Tuberculins (TRS 745) and European Pharmacopoeia: 0151.

INDICATIONS:

One single human dose for I.D. application is 0.1 ml

Stabilized Standard PPD solutions are ready to use for Mantoux's intradermal test (standard clinical dose is 5 TU/0.1 ml) to assist in clinical diagnosis of tuberculosis for :

- diagnosis and differential diagnosis of tuberculosis;
- early detection of tuberculosis in children;
- screening for infection by M.tuberculosis or atypical mycobacteria;
- examination for allergy acquired after BCG vaccination;
- identification of subjects for BCG revaccination.

CONTRAINDICATIONS:

Known hypersensitivity to the contents.

PRECAUTIONS FOR USE:

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Effective use of tuberculin testing requires an understanding of the characteristics inherent to the test and extrinsic factors relating that have influence on interpretation of the results.

A separate, sterile syringe and needle, or a sterile disposable unit, must be used for each patient to prevent the transmission of infectious agents from one person to another.

Needles should be recapped and should be disposed of according to applicable biohazard waste guidelines.

Special care should be taken to ensure the product is given intradermally and on the volar or dorsal aspect of the forearm, distance from blood vessels.

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

Do not inject intravenously or intramuscularly.

Do not inject subcutaneously. If this occurs, the test cannot be interpreted !

Pediatric use - There is no age contraindication to tuberculin skin testing of infants. Because their immune systems are immature, many infants < 6 weeks of age who are infected with *M. tuberculosis* do not react to tuberculin tests. Older infants and children develop tuberculin sensitivity 6 weeks or more after initial infection.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Tuberculin PPD has not been evaluated for its carcinogenic or mutagenic potentials or impairment of fertility.

Pregnancy Category C (Tuberculin)

Tuberculin skin testing is considered valid and safe throughout pregnancy.

No teratogenic effects of testing during pregnancy and lactation have been recorded .

HIV – infected persons

HIV – infected individuals should receive tuberculin skin testing as recommended.

In HIV-infected individuals, whose tuberculin skin-test results are less reliable as CD4 counts decline, screening should be completed as early as possible after HIV-

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infection occurs. Those HIV-infected patients at high risk for continuing exposure to patients who have TB should be screened periodically for TB infection. If they have TB symptoms or if they are exposed to a patient who has pulmonary TB, HIV-infected persons should be evaluated promptly for TB. Because active disease can develop rapidly in HIV-infected persons, the highest priority for contact investigation should be given to persons potentially co infected with HIV and TB.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

APPLICATION MODE AND DOSAGE:

Dosage and injection site.

The standard strength for diagnostic purpose is 5 TU Tuberculin PPD.

The dosage is always 0.1 ml I.D.

The dosage should be given **strictly** intradermally (intracutaneously) in the middle third of the forearm (volar or dorsal site), distance from blood vessels using a 1.0 ml graduated tuberculin syringe fitted with a short bevel needle, 25 or 26 gauge.

Injection technique

Use separate sterile needles and syringes for each patient.

The site of injection should be cleaned with alcohol, allowed to dry.

Fill the syringe immediately before use.

Draw up slightly more than 0.1 ml of Tuberculin PPD, remove any air bubbles and reduce the volume to exactly 0.1 ml.

Insert into the skin with the needle bevel up, entering just the superficial layer of the skin. While injecting, the syringe should be held parallel to the longitudinal axis of the forearm. The needle should be visible through the epidermis during insertion.

Inject the solution slowly and a small papule of 8-10 mm in diameter will appear and remain for about 10 minutes. If no papule is formed, the solution might have been injected too deeply, and the skin test should be repeated at another site, at least 4 or more centimeters away from the first injection.

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Evaluating the reaction

The result should be evaluated 72 hours after the injection.

A positive reaction to Tuberculin PPD is defined as a flat, uneven, slightly raised palpable induration with a diameter of at least 5 millimeters, surrounded by a more or less defined area of redness.

Only the induration should be recorded!

Diameter of induration

Negative	0-<5 mm
Positive	≥ 5 -15 mm
Strongly positive	> 15 mm

Reactions with a diameter larger than 15 mm are defined as strongly positive and give a strong indication of infection with *Mycobacterium tuberculosis complex*.

Previous vaccination with BCG or exposure to non tuberculous mycobacteria can give a positive reading due to cross reaction with common mycobacterial antigens.

Persons with induration less than 5 mm, have to be reimmunized with BCG vaccine (If BCG vaccination is included in National Immunization Programme).

Tuberculin reactivity may indicate prior infection and/or disease with *M. tuberculosis* and does not necessary indicate the presence of active tuberculous disease. Individuals showing tuberculin reactions considered positive by current public health guidelines should be evaluated by other diagnostic procedures, such as x-ray examination of the chest and microbiological examination of the sputum.

A negative test does not exclude active tuberculosis, especially if the test was done within six to eight weeks of acquiring the infection, if the infection is overwhelming, or if the patient is immunocompromised.

Very young age less than 6 months old or very old age; recent live viral vaccines (measles, mumps, rubella, oral polio, yellow fever, and varicella) within 4 to 6 weeks are other factors for possible negative skin test;

A false negative reaction may occur also:

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- After certain viral infection (eg. measles, rubella, varicella, granular fever etc.);
- Sever protein malnutrition, lymphoma, leukemia;
- After administration of persons with neoplastic diseases or sarcoidosis;
- After UV therapy;
- In those who are receiving corticosteroids or immunosuppressive agents;
- After administration of immunoglobulins.

In such cases tuberculin testing is not recommended.

Booster Effect

The “Booster Phenomenon” in Purified Protein Derivative (PPD) tuberculosis testing occurs when a person’s immune system has “forgotten” about an infection by *Mycobacterium tuberculosis* until years later when the person is tested again for tuberculosis; the PPD test “reminds” the immune system about the infection.

Although the initial PPD test was negative, a second PPD test performed year later, may “boost” the immune system’s ability to react to the tuberculin. Therefore, there is no way of knowing if the positive result was due to the booster phenomenon.

The best way to avoid this from happening is **to perform a two step test.**

The two-step tuberculin test involves a person getting re-tested one week after the initial Mantoux test. If both tuberculin tests are negative, the person is unlikely to have tuberculosis. Furthermore, if a future tuberculosis test is positive, it can be concluded that the tuberculosis infection is new and not due to the tuberculosis “booster phenomenon”.

SIDE EFFECTS:

There is a very small risk of severe redness and swelling in the arm.

Hyperergic subjects have occasionally been observed to develop lymphaginitis and lymphadenitis.

COMPATIBILITY WITH DRUGS AND BIOPRODUCTS:

Skin response to Tuberculin PPD may be diminished or abolished in subjects receiving corticosteroids or immunosuppressive agents; after immunization with live viral vaccines; after administration of immunoglobulins. In such cases tuberculin is not recommended.

NOTICE TO APPLICANTS
SUMMARY OF PRODUCT CHARACTERISTICS

PPD Tuberculin Mammalian

STORAGE:

In the dark at a temperature between +2°C and +8°C

DO NOT FREEZE. Discard product if exposed to freezing.

Keep out of the reach and sight of children

Multi-dose vials of Tuberculin PPD from which one or more doses have been removed, may be used for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: The use of opened multi dose vials in subsequent immunization sessions. (36). WHO/V&B/00.09:

- The expiry date has not passed;
- The Tuberculin PPD is stored under appropriate cold chain conditions (in the dark at temperature +2⁰C to +8⁰C);
- The product vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses;

EXPIRY DATE: 24 months.

Do not use after expiration date.

PRESENTATION:

1 ml (10 doses) containing 50 TU of PPD = 5 TU/0.1 ml

1,5 ml (15 doses) containing 75 TU of PPD=5TU/0.1 ml

2 ml (20 doses) containing 100 TU of PPD= 5 TU/0.1 ml

Tuberculin PPD solutions do not require future dilution.

Manufactured by: BB-NCIPD Ltd., 1504 Sofia, Bulgaria

Registration No. 20000719

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