S T A T E N S
S E R U M
I N S T I T U T

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PACKAGE LEAFLET:
INFORMATION FOR THE USER

Tuberculin PPD RT23 SSI solution for intradermal injection

Strengths: 2 T.U./0.1 ml and 10 T.U./0.1 ml

Tuberculin PPD RT23 SSI for Mantoux testing Solution for intradermal injection

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5, Artillerivej
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Denmark

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. WHAT TUBERCULIN PPD RT23 SSI IS AND WHAT IT IS USED FOR

This medicinal product is for diagnostic use only.

2. BEFORE YOU USE TUBERCULIN PPD RT23 SSI

Do not use Tuberculin PPD RT23 SSI
- if you are, allergic (hypersensitive) to tuberculin PPD or any of the other ingredients of Tuberculin PPD RT23 SSI.

Take special care with Tuberculin PPD RT23 SSI
- if you have had a Mantoux skin test within the last year, false positive reactions may appear.
- inform your doctor if you have been vaccinated against tuberculosis.
- inform your doctor if you have received other vaccinations e.g. against measles, mumps and rubella.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Tuberculin PPD RT23 with food and drink
No precautions regarding food and drink.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. The skin test may be carried out during pregnancy or breast-feeding.

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

Important information about some of the ingredients of Tuberculin PPR RT23 SSI
Not relevant.

3. HOW TO USE TUBERCULIN PPD RT23 SSI

Always use Tuberculin PPD RT23 SSI exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 0.1 ml for children as well as adults.

The injection should be given in the superficial layer of the skin of the forearm. 48 - 72 hours after the injection, the reaction will be examined.

The following information is intended for medical or healthcare professionals only:

Injection technique
0.1 ml Tuberculin PPD RT23 SSI should be administered with a 1 ml graduated syringe fitted with a short bevel needle (gauge 25 or 26). The injection should be given strictly intradermally in the middle third of the forearm, as a reaction might be weaker near the wrist or the elbow joint. The skin is slightly stretched, and the needle point (held almost parallel with the skin surface, bevel upwards) is inserted into the superficial layer of the dermis. The needle should be visible through the epidermis during insertion. The solution is slowly injected and a small papule of 8-10 mm in diameter appears and remains for about 10 minutes. If a papule does not appear the solution has been injected too deeply, and the test should be repeated on the other arm. If the same arm is used the injection site should be separated at least 4 cm from the first injection site.

The injection may result in an induration surrounded by an area of erythema a few hours after the injection.

Evaluating the reaction
The reaction should be evaluated 48-72 hours after the injection.

If you use more Tuberculin PPD RT23 SSI than you should
Since Tuberculin PPD RT23 SSI will be administered by doctor or nurse, it is very unlikely that you may receive too much or too little of the vaccine. If you think you may not have had the correct dose, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicine, Tuberculin PPD RT23 can cause side effects, although not everybody gets them

Common side effects (happens for more than 1 in a hundred patients)
Pain, irritation or discomfort at the injection site immediately after the injection.

Less common side effects (happens for less than 1 in a hundred patients)
Headache, fever and enlargements of the lymph node.

Rare side effects (happens for less than 1 in a thousand patients)
Anaphylactic reaction. This is indicated by a rash in form of urticaria, swelling around the eyes and in the face, difficulty in breathing and swallowing, itching on hands and feet.

Do these reactions occur a doctor must be called immediately. Hypersensitivity to tuberculin PPD can cause blisters and necrosis at the injections site.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TUBERCULIN PPD RT23 SSI

Store in a refrigerator (2°C – 8°C).

Store vial in original package in order to protect from light.

After first opening Tuberculin PPD RT23 SSI has to be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours when stored in a refrigerator (2°C to 8°C).

Do not use Tuberculin PPD RT23 SSI after the expiry date which is stated on the label as "EXP". The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of reach and sight of children.

6. FURTHER INFORMATION

What Tuberculin PPD RT23 SSI contains
- The active substance is tuberculin PPD RT23
  Tuberculin PPD RT23 SSI is marketed in different strengths:
- 2 T.U./0.1 ml which contains 0.04 microgram tuberculin PPD
- 10 T.U./0.1 ml which contains 0.2 microgram tuberculin PPD

- The other ingredients are: Disodium phosphate dihydrate, sodium chloride, potassium dihydrogen phosphate, potassium hydroxyquinoline sulphate, polysorbate 80 and water for injections.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

This medicinal product contains less than 1 mmol potassium (39 mg) per dose, i.e. essentially 'potassium-free'.

What Tuberculin PPD RT23 SSI looks like and contents of the pack
Tuberculin PPD RT23 SSI is a solution for intradermal injection. It is a clear colourless or pale yellow solution.

Pack sizes: Vials containing 1.5 ml or 5 ml in pack sizes of 1 or 10.

Not all pack sizes may be marketed.

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A positive reaction to Tuberculin PPD RT23 SSI is defined as a flat, uneven, slightly raised induration having a diameter of at least 6 mm, surrounded by a more less defined area of redness. *Only the Induration is assessed.* The diameter of the induration in millimetres are measured transversely to the long axis of the forearm with a clear, flexible, plastic ruler.

HOW TO READ THE MANTOUX TEST Diameter of induration in mm		
Negative	Positive	Strongly positive
0-5 mm	6-14 mm	15+ mm

A positive reaction indicates a response of the immune system due to one or more of the following reasons
a. infection with *Mycobacterium tuberculosis* complex *(M. tuberculosis, M. bovis, M. africanum or M. microti)*
b. infection with non-tuberculous mycobacteria
c. previous BCG vaccination (BCG vaccinated persons normally become tuberculin positive after 4-8 weeks)

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

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