Package leaflet: Information for the user

Tuberculin PPD RT23 AJV 2 T.U./0.1 mL
Solution for injection

Tuberculin PPD RT 23

Read all of this leaflet carefully before you are skin tested because it contains important information for you .
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tuberculin PPD RT23 AJV is and what it is used for

Tuberculin PPD RT23 AJV is used as a skin test to diagnose if you have ever been infected with a bacteria causing tuberculosis.

This medicine is for diagnostic use only.

2. What you need to know before you are skin tested

You should not be tested:
- if you are allergic to Tuberculin PPD RT 23 or any of the other ingredients of Tuberculin PPD RT23 AJV (listed in section 6).
- if you have experienced a severe local reaction to tuberculin products. A severe local reaction may include blistering and ulceration at the injection site and skin necrosis at the centre widespread tuberculin reaction. The necrosis will generally disappear after a few days.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before being tested with Tuberculin PPD RT23 AJV.

Inform your doctor:
- if you have had a tuberculin skin test within the last year.
- if you have been vaccinated within the last 4–6 weeks against tuberculosis or any other disease.

Other medicines and Tuberculin PPD RT23 AJV
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are skin tested.

The skin test can be carried out during pregnancy or breast-feeding.

Driving and using machines
Tuberculin PPD RT23 AJV has no or negligible influence on your ability to drive and use machines.

Tuberculin PPD RT23 AJV contains potassium and sodium
This medicinal product contains less than 1 mmol potassium (39 mg) and less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'potassium- and sodium-free'.

3. How you are skin tested

The doctor or nurse will inject Tuberculin PPD RT23 AJV in the upper layer of the skin of your forearm.

The recommended dose is 0.1 mL for children and adults.

After injection a papule of 8–10 mm in diameter will appear and remain for about 10 minutes. Redness and induration may appear at the injection site. After 48–72 hours the result of the skin test is examined by your doctor or nurse. If an induration has appeared it should decrease hereafter.

Detailed information on the method of administration and evaluation of the skin test is included in the section "The following information is intended for medical or healthcare professionals only".

If you have any further questions on the use of this test, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Very rare: may affect up to 1 in 10,000 people
- Serious allergic reactions (anaphylaxis) such as swelling of the lips, face and throat, breathing difficulty, and hives may occur in very rare cases. If you observe any of these reactions contact your doctor immediately.

Other side effects
Common: may affect up to 1 in 10 people
- Pain, itching and irritation at the injection site.

Uncommon: may affect up to 1 in 100 people
- Fever.
- Enlargement of the lymph nodes.

Rare: may affect up to 1 in 1,000 people
- Skin necrosis, will generally disappear after a few days.
- Blistering (vesiculation).

Not known: frequency cannot be estimated from the available data
- Ulceration at the injection site.
- Headache.
- Hives (urticaria).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tuberculin PPD RT23 AJV

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label as "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2ºC – 8ºC).

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

Tuberculin PPD RT23 AJV should be used immediately after opening. If not used immediately the in-use-storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C – 8°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tuberculin PPD RT23 AJV contains

- The active substance is: Tuberculin PPD RT 23.

  1 dose (0.1 mL) of Tuberculin PPD RT23 AJV 2 T.U. contains:
  0.04 microgram Tuberculin PPD RT 23

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

What Tuberculin PPD RT23 AJV looks like and contents of the pack

Tuberculin PPD RT23 AJV is a solution for injection (injection).
It is a clear, colourless to pale-yellow solution.

Tuberculin PPD RT23 AJV is marketed in one strength: 2 T.U.

Pack sizes: vials containing 1.5 mL in pack sizes of 1 or 10.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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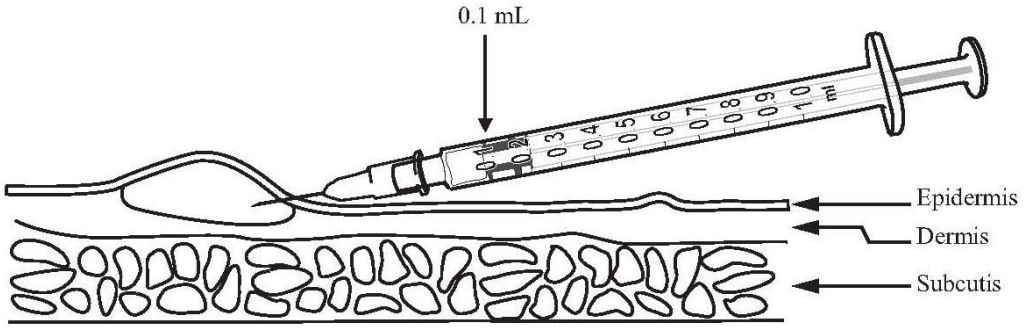
This leaflet was last revised in
Detailed information on this medicine is available on the web site of:
www.imb.ie (Home» Medicines» Human Medicines» Human Medicines Listing)

The following information is intended for healthcare professionals only:

Method of administration
In the following a detailed description of administration of Tuberculin PPD RT23 AJV is given:

- 0.1 mL is administered with a 1 mL graduated syringe fitted with a short bevel needle (gauge 25 or 26).
- The injection must be given strictly intradermally in the middle third of the forearm. Administration near the wrist or the elbow joint may weaken the reaction.
- The skin is slightly stretched, and the needle is held almost parallel with the skin surface with the bevel upwards. The tip of the needle is inserted into the superficial layer of the dermis.
- The needle should be visible through the epidermis during insertion. The 0.1 mL is slowly injected and a small blanched papule of 8–10 mm in diameter appears. This papule will disappear after approximately 10 minutes.
- If no papule appears, the injection has been given too deep, and the skin test should be repeated on the other arm or on the same arm, at least 4 cm away from the first injection site.



National recommendations regarding the administration of the Mantoux tuberculin skin test may be taken into consideration.

Evaluating the reaction
A skin test reaction is seen as a flat, uneven, slightly raised induration surrounded by an area of redness. The induration should be evaluated 48–72 hours after the injection and should decrease after this. Only the induration is assessed.

The diameter of the induration is measured in millimetres transversely to the long axis of the forearm with a transparent, flexible plastic ruler.

Recommendations for interpreting the Mantoux tuberculin skin test are shown in Table 1.

Diameter of induration in millimetres		
Negative 0–5 mm	Positive 6–14 mm	Strongly positive +15 mm

Table 1: Normal interpretation of the skin test result.

Alternative interpretations, depending on national recommendations, individual and epidemiological factors, may be applied.

Interpretation
A positive reaction indicates an immune response for one or more of the following reasons:

- Infection with *Mycobacterium tuberculosis* complex, including *M. tuberculosis, M. bovis, M. africanum, M. microtii*, or *M. tuberculosis subsp. caprae*.

- Infection with non-tuberculous mycobacteria.

- Previous BCG vaccination (BCG-vaccinated individuals normally become tuberculin-positive after 4–8 weeks).

Reactions larger than 15 mm are unlikely to be due to previous BCG vaccination or exposure to environmental mycobacteria.