PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Tuberculin PPD RT/23 2 TU / 0,1 ml solution for injection

Tuberculin PPD RT/23

Sugar free

Read all of this leaflet carefully before you receive Tuberculin PPD RT/23 2 TU / 0,1 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What Tuberculin PPD RT/23 2 TU / 0,1 ml is and what it is used for

Tuberculin PPD RT/23 2 TU / 0,1 ml is for diagnostic use only.

Tuberculin PPD RT/23 2 TU / 0,1 ml is used in a screening test (the tuberculin skin test) to determine if a person has been infected by the bacteria that causes 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.

2. What you need to know before you receive Tuberculin PPD RT/23 2 TU / 0,1 ml

Tuberculin PPD RT/23 2 TU / 0,1 ml should not be administered to you if:

- you are allergic (hypersensitive) to Tuberculin PPD RT/23 or any of the other ingredients of Tuberculin PPD RT/23 2 TU / 0,1 ml (listed in section 6).
- you have experienced a severe local reaction to a tuberculin medicine. A severe local reaction may include blistering and ulceration at the injection site and skin necrosis at the centre of a widespread tuberculin reaction. The necrosis will generally disappear after a few days.

- you have previously been diagnosed with tuberculosis or any other mycobacterial disease.

Warnings and precautions

Take special care with Tuberculin PPD RT/23 2 TU / 0,1 ml:

If you or your child are being tested and have any of the following conditions, talk to your healthcare provider BEFORE being tested with Tuberculin PPD RT/23 2 TU / 0,1 ml:

- Severe allergy to a previous tuberculin test.
- A weakened immune system due to medicines 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.

Other medicines and Tuberculin PPD RT/23 2 TU / 0,1 ml

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tuberculin PPD RT/23 2 TU / 0,1 ml can be safely administered simultaneously with vaccines. However reduced reactivity may be observed after vaccinations with vaccines against measles, mumps and rubella. This decreased reactivity may result in false-negative reactions. Previous BCG vaccination can result in a false-positive reaction.

A variety of host-related factors such as age, nutrition, kidney failure, diabetes, immunosuppression by medicinal products (e.g. corticosteroids) or disease, e.g. cancer, HIV infection or sarcoidosis can cause false-negative tuberculin reactions. Viral infections (particularly measles, mumps, mononucleosis, varicella and influenza) can lower the tuberculin reactivity for a few months.

For people scheduled to receive a tuberculin skin test, testing should be done either on the same day as vaccination or at least 4 - 6 weeks after administration of the live virus vaccine. Reduced tuberculin reactivity may be observed after vaccinations with live virus (e.g. vaccines against measles, mumps and rubella).
This decreased tuberculin reactivity may result in false-negative reactions. Therefore, if Mantoux tuberculin skin testing cannot be done at the same time as measles, mumps and rubella immunisation, the test should be postponed for 4 - 6 weeks.
Tuberculin PPD RT/23 2 TU / 0,1 ml can be safely administered simultaneously with all live and inactivated vaccines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive Tuberculin PPD RT/23 2 TU / 0,1 ml.

Tuberculin skin testing with Tuberculin PPD RT/23 2 TU / 0,1 ml is considered safe during pregnancy and breastfeeding.

Driving and using machines

Tuberculin PPD RT/23 2 TU / 0,1 ml has no or a minor influence on the ability to drive and use machines

3. How to receive Tuberculin PPD RT/23 2 TU / 0,1 ml

You will not be expected to give yourself Tuberculin PPD RT/23 2 TU / 0,1 ml. It will be given to you by a person who is qualified to do so.

Usual dose:

For each tuberculin skin test, 0,1 ml dose of Tuberculin PPD RT/23 2 TU / 0,1 ml is injected under the top layer of skin of the forearm. The tuberculin skin test involves 2 steps, and will require 2 visits to your healthcare provider.

During the first visit, a small amount of Tuberculin PPD RT/23 2 TU / 0,1 ml is injected into the topmost layers of skin on the inner forearm, causing a small bump. After injection a papule of 8 - 10 mm in diameter will appear and remain for about 10 minutes. Tuberculin PPD RT/23 2 TU / 0,1 ml contains proteins from the TB causing bacteria, which provoke a skin reaction at the site of injection 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 Tuberculin PPD

RT/23 2 TU / 0,1 ml. 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 Tuberculin PPD RT/23 2 TU / 0,1 ml was injected.

For some individuals, who are going to be retested periodically, such as healthcare workers, 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 Tuberculin PPD RT/23 2 TU / 0,1 ml 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 Tuberculin PPD RT/23 2 TU / 0,1 ml should be evaluated by other diagnostic procedures, such as X-ray examination of the chest and microbiological examination of a productive cough.

If you receive more Tuberculin PPD RT/23 2 TU / 0,1 ml than you should

Since a health care provider will administer Tuberculin PPD RT/23 2 TU / 0,1 ml, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Undesirable effects in relation to overdosage are not expected.

If you miss a dose of Tuberculin PPD RT/23 2 TU / 0,1 ml

Since a health care provider will administer Tuberculin PPD RT/23 2 TU / 0,1 ml, it is unlikely that the dose will be missed.

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

4. Possible side effects

Tuberculin PPD RT/23 2 TU / 0,1 ml can have side effects.

Not all side effects reported for Tuberculin PPD RT/23 2 TU / 0,1 ml are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving Tuberculin PPD RT/23 2 TU / 0,1 ml, please consult your ~~doctor, pharmacist or other~~ health care provider for advice.

If any of the following happens to you, after being administered Tuberculin PPD RT/23 2 TU / 0,1 ml tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Tuberculin PPD RT/23 2 TU / 0,1 ml. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common side effects (may affect up to 1 in 10 people):

- Pain, itching and irritation at the injection site.

Uncommon side effects (may affect up to1 in 100 people):

- Fever and enlargement of the lymph nodes.

Rare side effects (may affect up to 1 in 1 000 people):

- Skin necrosis will generally disappear after a few days, and blistering (vesiculation).

Not known (frequency cannot be estimated from the available data):

- Ulceration at the injection site, headache and hives (urticaria).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of Tuberculin PPD RT/23 2 TU / 0,1 ml.

5. How to store Tuberculin PPD RT/23 2 TU / 0,1 ml

Store all medicines out of reach of children.

- Store in a refrigerator (2 ºC – 8 ºC).
- Do not freeze.
- Store in the original package in order to protect from light.
- Do not use after the expiry date stated on the label.
- From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2°C – 8°C.
- Keep the vial in the carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tuberculin PPD RT/23 2 TU / 0,1 ml contains

- The active substance is Tuberculin PPD RT/23.

One single dose of Tuberculin PPD RT/23 2 TU / 0,1 ml contains 0,04 micrograms of Tuberculin PPD RT/23.

Preservative:

Potassium hydroxyquinoline sulphate 0,01 % *m/v*

Sugar free.

- The other ingredients are:

Disodium phosphate dihydrate, polysorbate 80, potassium dihydrogen phosphate, potassium hydroxyquinoline sulphate, sodium chloride, water for injections.

What Tuberculin PPD RT/23 2 TU / 0,1 ml looks like and contents of the pack

Solution for injection.

A clear, colourless to pale-yellow solution without particles.

Contents of the pack:

Tuberculin PPD RT/23 2 TU / 0,1 ml is packed as 1,5 ml solution in multi-dose glass vial (type I) closed with a stopper (chlorobutyl rubber) in pack sizes of 1 or 10.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd.

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South Africa

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Access to the corresponding Professional Information

To be confirmed.