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Siiltibcy (*rdESAT-6 and rCFP-10*)

An overview of Siiltibcy and why it is authorised in the EU

What is Siiltibcy and what is it used for?

Siiltibcy is used to help detect infection and disease caused by *Mycobacterium tuberculosis* in adults and children aged 4 weeks and older.

Siiltibcy contains the active substances rdESAT-6 and rCFP-10, two proteins from the *M. tuberculosis* bacterium.

How is Siiltibcy used?

Siiltibcy can only be obtained with a prescription.

Siiltibcy is given as an injection in the skin of the forearm. It should be prepared and given by a trained healthcare professional, using a technique called the Mantoux technique.

The injection causes induration (hardening) at the site. By measuring the size of the induration, 48 to 72 hours after the injection, the doctor will determine if the person is infected by *M. tuberculosis* or has tuberculosis (the disease caused by *M. tuberculosis*).

For more information about using Siiltibcy, see the package leaflet or contact your doctor or pharmacist.

How does Siiltibcy work?

Siiltibcy contains two proteins from the bacterium *M. tuberculosis* that have been produced in a laboratory. If a person has been infected with *M. tuberculosis*, an injection of Siiltibcy will activate the immune system, which leads to inflammation at the site of injection, seen as an induration. An induration size over 5 millimetres 48 to 72 hours after injection indicates an infection.

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What benefits of Siiltibcy have been shown in studies?

Three main studies involving a total of 2,625 people, including children, compared Siiltibcy with two authorised diagnostic tests for detecting *M. tuberculosis*: purified tuberculin derivative (referred to as PPD), which uses the same skin injection technique as Siiltibcy; and QuantiFERON-TB Gold in-Tube, referred to as QFT, which uses blood samples.

The first two studies involved people who had either never been exposed to *M. tuberculosis* or were highly suspected of having tuberculosis. The third study involved people with confirmed tuberculosis.

The data showed that as exposure to *M. tuberculosis* increased, the likelihood of Siiltibcy providing a positive diagnosis also increased.

In addition, the studies compared the ability of the three tests to detect positive results in individuals with confirmed tuberculosis, a measure known as test sensitivity. Sensitivity of Siiltibcy was between 68 and 79% in the three studies. This was generally lower than sensitivity of PPD and comparable to that of QFT.

The studies also compared the ability of the three tests to detect negative results in individuals known to be negative (never exposed to *M. tuberculosis*), a measure known as test specificity. The specificity of Siiltibcy ranged between 83 and 97%, which was slightly better than either PPD or QFT.

What are the risks associated with Siiltibcy?

For the full list of side effects and restrictions with Siiltibcy, see the package leaflet.

The most common side effects with Siiltibcy include pruritus (itching) at the injection site (which may affect about 1 in 5 people), haematoma (bruises) and pain at the injection site (which may affect up to 1 in 10 people).

Siiltibcy must not be used in people who are hypersensitive (allergic) to the bacteria *Lactococcus lactis* (as it is used to make Siiltibcy), or to the active substances or other ingredients of Siiltibcy. It must also not be used in people who have had a severe local (skin) reaction or general (affecting anywhere in the body) reaction to other tuberculosis skin tests.

Why is Siiltibcy authorised in the EU?

Three main studies have shown that Siiltibcy can help detect infection with *M. tuberculosis,* including detection in people with tuberculosis. It therefore represents an alternative to other widely used tests for detecting this infection. Siiltibcy is easier to use than QFT. Although Siiltibcy was less sensitive than PPD, it had a higher specificity in people previously vaccinated with the Bacillus Calmette-Guérin (BCG) vaccine.

Overall, the safety profile of Siiltibcy is favourable and expected to be manageable, as most local reactions were mild or moderate.

The European Medicines Agency therefore decided that Siiltibcy's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Siiltibcy?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Siiltibcy have been included in the summary of product characteristics and the package leaflet.

Data on the use of Siiltibcy are continuously monitored. Suspected side effects reported with Siiltibcy are carefully evaluated and any necessary action taken to protect patients.

Other information about Siiltibcy

Siiltibcy received a marketing authorisation valid throughout the EU on 13 January 2025.

Further information on Siiltibcy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/siiltibcy.

This overview was last updated in 01-2025.