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Questions and answers

Withdrawal of the marketing authorisation application for Solithromycin Triskel EU Services (solithromycin)

On 27 March 2017, Triskel EU Services Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Solithromycin Triskel EU Services, intended for the treatment of community-acquired pneumonia, inhaled anthrax and inhaled tularaemia.

What is Solithromycin Triskel EU Services?

Solithromycin Triskel EU Services is a medicine that contains the active substance solithromycin. It was to be available as capsules to be taken by mouth and as a powder to be made into a solution for infusion (drip) into a vein.

What was Solithromycin Triskel EU Services expected to be used for?

Solithromycin Triskel EU Services was expected to be used to treat the following bacterial infections:

- community-acquired pneumonia (an infection of the lungs caught outside of hospital);
- inhaled anthrax (the most serious form of anthrax caught by inhaling bacterial spores);
- inhaled tularaemia (another serious disease caught by inhaling bacteria).

How does Solithromycin Triskel EU Services work?

The active substance in Solithromycin Triskel EU Services, solithromycin, is a type of antibiotic similar to a group of antibiotics known as ‘macrolides’. It works by blocking the production of bacterial proteins, thus preventing the growth of the bacteria.

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What did the company present to support its application?

The company presented data from three studies in a total of 1,855 patients with community-acquired pneumonia, in which Solithromycin Triskel EU Services was compared with other antibiotics (levofloxacin and moxifloxacin). No studies in patients with inhaled anthrax or inhaled tularaemia have been carried out and the company presented data from laboratory studies.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had several concerns and was of the provisional opinion that Solithromycin Triskel EU Services could not have been approved for the treatment of community-acquired pneumonia, inhaled anthrax and inhaled tularaemia.

The CHMP was concerned that not enough data had been provided to support use in inhaled anthrax and inhaled tularaemia. There were also concerns that solithromycin could be harmful to the liver. In addition, it had concerns about the manufacturing process of the active substance, which did not exclude the presence of impurities, and the test for ensuring sterility of the product for infusion was not considered valid.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Solithromycin Triskel EU Services did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that its decision to withdraw is based on a request from the US FDA to provide additional safety data to support approval in the US. The company plans to include these data in a new marketing authorisation application in the EU.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Solithromycin Triskel EU Services.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.