



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Obiltoxaximab SFL (*obiltoxaximab*)

An overview of Obiltoxaximab SFL and why it is authorised in the EU

What is Obiltoxaximab SFL and what is it used for?

Obiltoxaximab SFL is a medicine used with antibiotic treatment to treat inhalational anthrax, a serious disease caused by the bacteria *Bacillus anthracis*. 'Inhalational' means that the person catches the disease by breathing in spores, which develop into active bacteria in the body and release harmful toxins.

The medicine is also used to prevent inhalational anthrax in people who have come into contact with the bacteria spores and when no other appropriate treatment is available.

Obiltoxaximab SFL contains the active substance obiltoxaximab.

Anthrax is rare, and Obiltoxaximab SFL was designated an 'orphan medicine' (a medicine used in rare diseases) on 24 August 2018. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3182065.

How is Obiltoxaximab SFL used?

Obiltoxaximab SFL can only be obtained with a prescription and should be given in a place where severe allergic reactions can be quickly treated.

Obiltoxaximab SFL is given as a single infusion (drip) into a vein over 90 minutes. The recommended dose depends on the patient's weight. Before Obiltoxaximab SFL is given, patients may be given medicines to prevent or reduce allergic reactions.

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

How does Obiltoxaximab SFL work?

The serious effects of anthrax are caused by a toxin that the anthrax bacteria produce. Obiltoxaximab is a monoclonal antibody, a type of protein, which has been designed to attach to a component of the anthrax toxin called 'anthrax protective antigen' that allows the toxin to enter cells. By attaching to anthrax protective antigen, the medicine is expected to stop the toxin from entering the body's cells, thereby reducing or preventing symptoms.

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What benefits of Obiltoxaximab SFL have been shown in studies?

Obiltoxaximab SFL is considered effective at treating inhalational anthrax based on studies in animals. In 3 studies in infected animals with symptoms, the survival rates ranged between around 30 and 60% with Obiltoxaximab SFL, compared with 0 to 6% with placebo (dummy treatment). In a study where infected animals received the medicine or placebo before developing symptoms, survival ranged between 50 and 100% with Obiltoxaximab SFL, depending on how soon the animals received treatment after being infected, compared with none of those given placebo.

What are the risks associated with Obiltoxaximab SFL?

The most common side effects with Obiltoxaximab SFL (which may affect up to 1 in 10 people) are headache, pruritus (itching), urticaria (itchy rash), rash, cough, infusion site pain and feeling dizzy.

For the full list of side effects and restrictions of Obiltoxaximab SFL, see the package leaflet.

Why is Obiltoxaximab SFL authorised in the EU?

Inhalation anthrax is a life-threatening disease leading to death in 50% of cases. Although natural outbreaks are very rare, infections can occur by accident in laboratories studying the bacteria, and anthrax might be used in terrorist attacks. Because the number of cases is so low and deliberately infecting individuals is too dangerous, it is not feasible to carry out studies of the medicine in people. Studies in animals showed that the medicine is effective at treating anthrax and preventing death, and it is expected that Obiltoxaximab SFL will work in the same way in people. In terms of safety, the side effects of Obiltoxaximab SFL in healthy people are usually mild or moderate. The Agency therefore decided that Obiltoxaximab SFL's benefits are greater than its risks and it can be authorised for use in the EU.

Obiltoxaximab SFL has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Obiltoxaximab SFL due to the rarity of the disease and for ethical reasons. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Obiltoxaximab SFL?

Since Obiltoxaximab SFL has been authorised under exceptional circumstances, the company that markets Obiltoxaximab SFL will provide further data on methods for measuring how the medicine is absorbed, modified and removed from the body in laboratory studies. In addition, data on the effectiveness and safety of the medicine during a potential outbreak of anthrax should be submitted.

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

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

As for all medicines, data on the use of Obiltoxaximab SFL are continuously monitored. Side effects reported with Obiltoxaximab SFL are carefully evaluated and any necessary action taken to protect patients.

Other information about Obiltoxaximab SFL

Obiltoxaximab SFL received a marketing authorisation valid throughout the EU on 18.11.2020.

Further information on Obiltoxaximab SFL can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/Obiltoxaximab-SFL

This overview was last updated in 11-2020.

Medicinal product no longer authorised