



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Ubac (*Streptococcus uberis* vaccine, inactivated)

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

What is Ubac and what is it used for?

Ubac is a vaccine used in cows and heifers (female cattle that have not yet calved) to reduce clinical mastitis (udder infections with visible signs in milk or the udder) caused by bacteria called *Streptococcus uberis*, which can reduce milk production. Ubac is also used to reduce the somatic cell count (SCC) in milk, which is a measure of mastitis without visible signs (subclinical mastitis). Ubac contains the active substance called biofilm adhesion component including lipoteichoic acid, which is derived from the sticky film produced by *Streptococcus uberis* strain 5616.

How is Ubac used?

Ubac is available as an injection and can only be obtained with a prescription. Ubac is given as a course of 3 injections into the neck muscles, alternating sides of the neck. The first injection is given at about 60 days before the expected calving date followed by a second injection given at least 3 weeks before the expected calving date. The third injection is given about 15 days after calving. The whole herd should be vaccinated. The full course should be repeated with each pregnancy. Protection starts about 36 days after the second injection and lasts for the first 5 months of lactation (milk production).

For more information about using Ubac, see the package leaflet or contact your veterinarian or pharmacist.

How does Ubac work?

Ubac is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The active substance in Ubac is obtained from the sticky substances that the *S. uberis* bacteria produce to protect themselves and attach to surfaces (known as biofilm adhesion components). When Ubac is given to cattle, the animals' immune system recognises the active substance as 'foreign' and makes antibodies against it. In the future, if the animals are exposed to disease-causing *S. uberis* bacteria, the immune system will be able to respond more quickly. This will help protect the cattle against the infection and reduce the risk of mastitis.



The vaccine also contains 'adjuvants' (Montanide ISA and MPLA) to stimulate a better reaction by the immune system.

What benefits of Ubac have been shown in studies?

A field study involved 6 farms with a history of *S. uberis* clinical mastitis and recently confirmed presence of *S. uberis* infection. During a 21 week observation period the incidence of new cases of *S. uberis* clinical mastitis was 50% lower in the group of 277 cattle vaccinated with Ubac compared to the group of 303 cattle given placebo (dummy treatment) (6.1% versus 12.2%).

What are the risks associated with Ubac?

The most common side effects with UBAC (which may affect more than 1 in 10 animals) are a short-lived increase in rectal temperature of around 1 - 2 °C within 24 hours of injection and a local injection site swelling of more than 5 cm in diameter. The injection site swelling usually disappears or reduces in size by 17 days after vaccination but in some cases the swelling may last for up to 4 weeks.

For the full list of restrictions, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – this could result in the loss of the finger if prompt medical attention is not given. If someone is accidentally injected with this product, they must seek medical attention immediately even if only a very small amount is injected. The package leaflet should be shown to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of a medicine before milk may be used for human consumption.

The withdrawal period for meat and milk from cattle treated with Ubac is 'zero' days, which means that there is no mandatory waiting time.

Why is Ubac authorised in the EU?

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

Other information about Ubac

Ubac received a marketing authorisation valid throughout the EU on 26 July 2018.

Further information on Ubac can be found on the Agency's website: ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports.

This overview was last updated in May 2018.