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EPAR summary for the public

ZULVAC 1+8 Ovis

Inactivated adjuvanted vaccine against bluetongue disease virus, serotypes 1 and 8

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is ZULVAC 1+8 Ovis?

ZULVAC 1+8 Ovis is a vaccine that contains inactivated (killed) bluetongue serotypes 1 and 8 viruses as the active substance. It is available as a suspension for injection.

What is ZULVAC 1+8 Ovis used for?

ZULVAC 1+8 Ovis is used in sheep to protect them against bluetongue disease, an infection caused by the bluetongue virus which is transmitted by midges. The virus exists in several forms (serotypes) throughout the world; the types used in ZULVAC 1+8 Ovis are serotypes 1 and 8. The vaccine is used to prevent viraemia (the presence of the virus in the blood) in sheep from one and a half months of age.

The vaccine is given to young animals as two injections under the skin. The first injection is given from one and a half months age and the second injection is given three weeks later. Protection starts three weeks after the last injection and lasts for one year.

How does ZULVAC 1+8 Ovis work?

ZULVAC 1+8 Ovis is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. ZULVAC 1+8 Ovis contains bluetongue viruses that

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have been inactivated so that they cannot cause the disease. When it is given to sheep and cattle, the immune system recognises the viruses as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to the bluetongue virus, the immune system will be able to produce antibodies more quickly. This will help to protect against the disease.

The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to enhance the immune response.

How has ZULVAC 1+8 Ovis been studied?

The safety of the vaccine was studied in two main laboratory safety studies carried out in sheep (overdose and single and repeated administration) and two studies carried out in pregnant ewes. The vaccine was generally well tolerated as demonstrated by the absence of major systemic reactions.

The efficacy of the vaccine was studied in four main laboratory trials in sheep of young age where animals were challenged with both BTV-1 and BTV-8 serotypes using ZULVAC 1-8 Ovis vaccines containing low antigen quantities.

What benefit has ZULVAC 1+8 Ovis shown during the studies?

The studies showed that the vaccine is safe for sheep and it prevents viraemia caused by bluetongue Virus, serotypes 1 and 8 in animals from one and a half months of age.

The studies also showed that the vaccine can be used in pregnant sheep.

What is the risk associated with ZULVAC 1+8 Ovis?

Sheep may show a temporary increase in rectal temperature, not more than 1.2 °C in the 24 hours following vaccination. There may be a local reaction at the injection site, such as swelling (lasting no more than one week) or 'nodules' (hardening under the skin) possibly lasting more than six or seven weeks.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine before the animal can be slaughtered and the meat or milk used for human consumption. The withdrawal period for ZULVAC 1+8 Ovis for meat and milk is zero days.

Why has ZULVAC 1+8 Ovis been approved?

The CVMP concluded that the benefits of ZULVAC 1+8 Ovis outweigh the risks for the prevention of viraemia caused by bluetongue virus, serotypes 1 and 8 in sheep from 1.5 months of age. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

ZULVAC 1+8 Ovis was initially authorised under 'exceptional circumstances'. This means that it was not possible to obtain complete information about ZULVAC 1+8 Ovis at the time of the initial authorisation. The European Medicines Agency (EMA) reviewed additional information submitted according to an agreed timetable on the quality, safety and efficacy of the vaccine. In 2013 the CVMP considered that the submitted data were adequate for the authorisation of ZULVAC 1+8 Ovis to convert to a normal status.

Other information about ZULVAC 1+8 Ovis:

The European Commission granted a marketing authorisation valid throughout the European Union, for ZULVAC 1+8 Ovis on 14 March 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in May 2013.