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EPAR summary for the public

ZULVAC 8 Ovis

Inactivated vaccine against Bluetongue disease virus, serotype 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 8 Ovis?

ZULVAC 8 Ovis is a vaccine that contains inactivated (killed) bluetongue serotype 8 virus as the active substance. It is available as a suspension for injection.

What is ZULVAC 8 Ovis used for?

ZULVAC 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 type used in ZULVAC 8 Ovis is serotype 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 animals as an injection under the skin. The first injection is given from one and a half months of age and the second injection is given three weeks later. Protection starts 25 days after the last injection and lasts for at least a year.

How does ZULVAC 8 Ovis work?

ZULVAC 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 8 Ovis contains bluetongue viruses that have been inactivated so that they cannot cause the disease. When it is given to sheep, the immune system recognises the viruses as 'foreign' and makes antibodies against them. In the future, if the animals are

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exposed to the bluetongue virus, the immune system will be able to produce antibodies more quickly. This will help them to protect against the disease.

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

How has ZULVAC 8 Ovis been studied?

The safety of the vaccine was studied in laboratory safety studies carried out with ZULVAC 8 Ovis in sheep. Results from a series of laboratory safety trials performed with vaccines of similar composition but containing different serotypes of the virus were also presented.

The effectiveness of the vaccine in preventing viraemia in sheep was studied in a laboratory trial using the vaccine in sheep from one month of age. The company also presented results from a series of studies with other vaccines that contain other serotypes of the bluetongue virus, as well as preliminary results from a study in sheep investigating how long the immunity produced by the vaccine lasted after vaccination.

What benefit has ZULVAC 8 Ovis shown during the studies?

The studies showed that the vaccine is safe for sheep and that it prevents viraemia in animals from one and a half months of age that are infected with bluetongue virus serotype 8.

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

What is the risk associated with ZULVAC 8 Ovis?

Sheep may show a temporary increase in body temperature, no more than 1.2°C, in the 24 hours after vaccination. There may also be a local reaction at the injection site, such as swelling (generally lasting less than a week) or 'nodules' (hardening under the skin) that may last for more than 6 or 7 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 8 Ovis for meat and milk is zero days.

Why has ZULVAC 8 Ovis been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of ZULVAC 8 Ovis exceed the risks in the prevention of viraemia caused by the bluetongue virus serotype 8 in sheep from one and a half months of age. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

ZULVAC 8 Ovis was initially authorised under 'exceptional circumstances'. This means that it was not possible to obtain complete information about ZULVAC 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 8 Ovis to convert to a normal status.

Other information about ZULVAC 8 Ovis:

The European Commission granted a marketing authorisation valid throughout the EU for ZULVAC 8 Ovis on 15 January 2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in April 2013.