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EPAR summary for the public

Zulvac 1+8 Bovis

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 Bovis?

Zulvac 1+8 Bovis 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 Bovis used for?

Zulvac 1+8 Bovis is used in cattle 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 Bovis are serotypes 1 and 8. The vaccine is used to prevent viraemia (the presence of viruses in the blood) in cattle from three months of age.

The vaccine is given to young animals as two injections under the skin. The first injection is given from three months of 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 Bovis work?

Zulvac 1+8 Bovis 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 Bovis contains bluetongue viruses that have been inactivated so that they cannot cause the disease. When it is given to cattle, the animals'

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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 them against the disease. The vaccine also contains ‘adjuvants’ (aluminium hydroxide and saponin) to enhance the immune response.

How has Zulvac 1+8 Bovis been studied?

Zulvac 1+8 Bovis was studied in calves in four main studies carried out in a laboratory. The studies looked at the strength of vaccine required to protect against bluetongue infection, and at the safety of the vaccine.

Another laboratory study in cattle looked at how long the vaccine was able to protect against bluetongue infection.

A field study was also conducted investigating the safety of the vaccine in dairy cows, including pregnant and lactating cows.

What benefit has Zulvac 1+8 Bovis shown during the studies?

The studies showed that the vaccine is safe and that it prevents viraemia caused by bluetongue virus serotypes 1 and 8 in cattle from three months of age. The field study showed that the vaccine can be used safely in pregnant and lactating cows.

What is the risk associated with Zulvac 1+8 Bovis?

Cattle may show a temporary increase in body temperature (no more than 2.7 °C) in the 48 hours following vaccination. Local reactions at the injection site are common and normally resolve within 4 weeks. Local reactions may increase slightly following the second dose, in this case lasting up to 15 days.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat or milk used for human consumption.

The withdrawal period for Zulvac 1 + 8 Bovis for meat and milk is zero days.

Why has Zulvac 1+8 Bovis been approved?

The CVMP concluded that the benefits of Zulvac 1+8 Bovis exceed the risks for prevention of viraemia caused by bluetongue virus serotypes 1 and 8 in cattle from three months of age and recommended that Zulvac 1+8 Bovis be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Zulvac 1+8 Bovis was initially authorised under ‘exceptional circumstances’. This means that it was not possible at the time of the initial authorisation to obtain complete information about Zulvac 1+8 Bovis. 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 Bovis to convert to a normal status.

Other information about Zulvac 1+8 Bovis:

The European Commission granted a marketing authorisation valid throughout the European Union for Zulvac 1+8 Bovis on 08/03/2012. Information on the prescription status of this product can be found on the label/outer package.

This summary was last updated in September 2013.