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EPAR summary for the public

ZULVAC 8 Bovis

Inactivated vaccine against Bluetongue 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 Bovis?

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

What is ZULVAC 8 Bovis used for?

ZULVAC 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 vaccine is used to prevent viraemia (the presence of the virus in the blood) in cattle from three months of age.

The vaccine is given to animals as an injection in the muscle. The first injection is given from three months of age and the second injection is given three weeks later. Protection starts from 25 days after the last injection and lasts for at least a year.

How does ZULVAC 8 Bovis work?

ZULVAC 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 8 Bovis contains bluetongue viruses that have been inactivated so that they cannot cause the disease. When it is given to 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.

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This will help them to protect against the disease.

ZULVAC 8 Bovis contains bluetongue virus of one type (serotype 8). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to enhance the immune response.

How has ZULVAC 8 Bovis been studied?

The safety of the vaccine was studied in laboratory safety studies carried out with ZULVAC 8 Bovis in cattle. Results from a series of laboratory safety trials performed with a vaccine of similar composition containing serotypes 1 and 8 and of studies performed with a vaccine of the same composition but of different serotype, used in sheep were presented in order to extrapolate safety conclusions.

The efficacy of the vaccine in cattle was studied in a laboratory trial using the vaccine in calves from two and a half months of age. Another laboratory study looked at the duration of the immunity following vaccination with ZULVAC 8 Bovis.

What benefit has ZULVAC 8 Bovis shown during the studies?

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

What is the risk associated with ZULVAC 8 Bovis?

After the second injection, animals may show a slight, temporary increase in body temperature of 0.4 ºC, in the 24 hours after vaccination.

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 Bovis for meat and milk is zero days.

Why has ZULVAC 8 Bovis been approved?

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

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

Other information about ZULVAC 8 Bovis:

The European Commission granted a marketing authorisation valid throughout the EU for ZULVAC 8 Bovis 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.