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EPAR summary for the public

Bovilis BTV8

Inactivated adjuvanted 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 Bovilis BTV8?

Bovilis BTV8 is a vaccine that contains an inactivated (killed) bluetongue serotype 8 virus as the active substance. It is available as a suspension for injection.

What is Bovilis BTV8 used for?

Bovilis BTV8 is used in cattle and 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 Bovilis BTV8 is serotype 8. The vaccine is used to prevent viraemia (the presence of viruses in the blood) in sheep and to limit viraemia in cattle.

The vaccine is given to young animals as an injection under the skin. One injection is enough to vaccinate sheep, but cattle will need a second injection approximately three weeks later. The first injection is given from one month of age in sheep and from six weeks of age in cattle.

How does Bovilis BTV8 work?

Bovilis BTV8 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Bovilis BTV8 contains bluetongue virus that has been inactivated so that it cannot cause the disease. When it is given to cattle and sheep, the animals' immune system recognises the virus as 'foreign' and produce antibodies against it. In the future, if the

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animals are exposed to the same type of 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 Bovilis BTV8 been studied?

The safety of the vaccine was studied in laboratory safety studies carried out with an overdose of Bovilis BTV8 in young lambs and calves and in pregnant ewes and cows.

The efficacy of the vaccine in cattle and sheep was studied in a number of laboratory trials; in cattle from six weeks of age and in sheep from one month of age.. The main measure of effectiveness was the level of the bluetongue virus in the blood (viraemia) of animals. In all studies, the vaccinated cattle and sheep were compared with animals that were not immunised (controls). The risk of bluetongue transmission to cattle following vaccination with Bovilis BTV8 was further investigated in two epidemiological models.

What benefit has Bovilis BTV8 shown during the studies?

The studies showed that the vaccine is safe for both sheep and cattle and that it prevents viraemia in sheep from one month of age when infected with bluetongue virus serotype 8, whereas Bovilis BTV8 reduces viraemia in cattle from six weeks of age.

Bovilis BTV8 was shown to be safe for use in pregnant ewes and cattle.

What is the risk associated with Bovilis BTV8?

After vaccination, animals may have a slightly raised temperature (usually not more than 0.5°C, but in individual cases up to about 2°C) for up to three days after vaccination. There can also be a temporary swelling at the injection site, lasting for up to three weeks in sheep and six weeks in cattle. Some animals may also have hypersensitivity (allergic) reactions.

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 both sheep and cattle for meat and milk is zero days.

Why has Bovilis BTV8 been approved?

The CVMP concluded that the benefits of Bovilis BTV8 exceed the risks and recommended that Bovilis BTV8 be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Bovilis BTV8 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 Bovilis BTV8. The European Medicines Agency (EMA) reviewed additional information according to an agreed timetable on the quality, safety and efficacy of the vaccine.

Other information about Bovilis BTV8:

The European Commission granted a marketing authorisation valid throughout the European Union, for Bovilis BTV8 on 06/09/2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2014.