EMA/626078/2014
EMEA/V/C/003703

EPAR summary for the public

Bovela

Bovine viral diarrhoea vaccine (modified live)

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 Bovela?

Bovela is a veterinary vaccine that contains two types of a modified live bovine viral diarrhoea (BVD) virus (BVDV-1 and BVDV-2). It is available as a lyophilisate (freeze dried powder) and solvent for injection.

What is Bovela used for?

Bovela is used to protect cattle against BVD viral infection. In non-pregnant animals the infection is generally mild, with signs affecting the airways such as cough, and reduced milk yield. However a severe form of BVD can occur, when cattle have a high temperature and bloody diarrhoea. In pregnant cows, BVD infection can cause abortions or result in the birth of calves that are persistently infected (PI). PI animals tend never to reach their productive potential, have reduced fertility and are more susceptible to other diseases. They may progress to have mucosal disease which is another form of BVD disease with ulcers and blisters on the snout and inside of the mouth. Mucosal disease is usually fatal. PI animals are a constant source of BVD virus, infecting other cattle in the herd.

The vaccine is given to cattle as a single injection into the muscle. Protection starts three weeks after vaccination and lasts for one year. To prevent the birth of a PI calf the vaccine should be given at least three weeks before insemination/mating.

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How does Bovela work?

Bovela is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Bovela contains two BVDV strains (or types) modified by deletion of parts of two genes so that they can no longer cause disease. When Bovela is given to cattle the animals' immune system recognises the virus strains as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to the virus the immune system will be able to respond more quickly. This will help protect the cattle against BVD infections.

How has Bovela been studied?

The effectiveness of the vaccine was first studied in a number of laboratory studies in cattle. The purpose of the studies was to establish how long it took for cattle to be fully protected, the length of time protection against BVD lasts, as well as the influence of maternal antibodies (transmitted from the mother) on the effectiveness of the vaccine in calves.

The effectiveness of Bovela was further investigated in the field in eight dairy cattle herds of which five of them had a history of BVD or persistent infection at the beginning of the study. Approximately half of the cattle were vaccinated with Bovela and the rest received a dummy injection. The main measure of effectiveness was the reduction in the number of persistently infected newborn calves as determined by virus specific identification tests.

What benefit has Bovela shown during the studies?

In the laboratory studies Bovela prevented PI in 100% of calves while the animals that received no vaccination gave birth to 100% PI calves.

In the field study 98.5% of vaccinated cattle sampled (range 269–274 animals) developed antibodies to both BVD virus types. In the group vaccinated with Bovela five out of 1,216 (0.4%) newborn calves were persistently infected with the virus, whereas in the group given the dummy injection there were ten persistently infected newborn calves out of 1,183 born (0.8%). However, for the vaccinated group the period of infection was either before vaccination or before the start of protection.

What is the risk associated with Bovela?

The most common side effect (seen in more than 1 in 100 cattle) was an increase in body temperature (within the normal range) within four hours of vaccination, which spontaneously resolves within 24 hours.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

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 used for human consumption or milk used for human consumption. The withdrawal period for Bovela for cattle is zero days.

Why has Bovela been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Bovela exceed the risks for the approved indication and recommended that Bovela be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Bovela:

The European Commission granted a marketing authorisation valid throughout the European Union, for Bovela on 22 December 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in October 2014.