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EPAR summary for the public

Hiprabovis IBR Marker Live

Live vaccine against infectious bovine rhinotracheitis (IBR)

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 Hiprabovis IBR Marker Live?

Hiprabovis IBR Marker Live is a vaccine. It is a powder for suspension for injection that contains a modified live infectious bovine rhinotracheitis (IBR) virus (also known as Bovine Herpes Virus type 1).

What is Hiprabovis IBR Marker Live used for?

Hiprabovis IBR Marker Live is used to vaccinate cattle (cows and calves) against the respiratory infections caused by IBR. The vaccine is used to reduce the clinical signs of IBR and the excretion (shedding) of the virus by the infected animals.

The vaccine is given to animals as two injections, three weeks apart, into the neck muscles. The first injection can be given to calves from three months of age. The injections should be preferably administered on the alternate sides of the neck. Afterward a single 'booster' can be given every six months to maintain the vaccine's effect.

How does Hiprabovis IBR Marker Live work?

Hiprabovis IBR Marker Live is a vaccine that contains an IBR virus that has been genetically modified to delete two genes so that the virus is less 'pathogenic' (less able to cause a disease). The virus is alive, but it has also been attenuated (weakened) to further lower its ability to cause infection.

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Hiprabovis IBR Marker Live is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Hiprabovis IBR Marker Live is given to cattle, the animals' immune systems recognise the viruses as 'foreign' and make defences against it. In the future, if the animals are exposed to the IBR virus, the immune system will be able to respond more quickly. This will help to protect against the disease.

How has Hiprabovis IBR Marker Live been studied?

The safety of Hiprabovis IBR Marker Live was investigated in a number of laboratory studies and in one field trial that included dairy cows and fattening cattle. Studies also looked at the safety of the vaccine in pregnant animals.

The efficacy of the vaccine was studied in three laboratory studies including one study looking at the duration of immunity. A field study also looked at the efficacy of Hiprabovis IBR Marker Live, compared with a dummy vaccine, on reducing the clinical signs of the disease and virus excretion.

What benefit has Hiprabovis IBR Marker Live shown during the studies?

The studies showed that the vaccine is safe for cattle from three months of age and that it reduces the clinical signs of IBR and field virus excretion. The studies also showed that the vaccine can be used in pregnant cattle as well in the presence of maternally derived antibodies. This vaccine is a marker vaccine and can enable a differential testing of vaccinated and naturally infected cattle, which is a useful tool in eradication campaigns.

What is the risk associated with Hiprabovis IBR Marker Live?

After vaccination, animals may show a slight increase in body temperature up to 1° C, in the four days following vaccination. This increase can sometimes be higher (up to 1.6º C in adult cows and up to 2.2º C in calves). The rise in temperature is temporary and spontaneously resolved within two days without treatment. Animals can also show a temporary inflammation at the site of injection in the 72 hours after-vaccination. This slight swelling lasts for less than a day in most cases.

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

There are no specific risks for the user.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

The withdrawal period is zero days.

What is the time to allow before milk can be taken from the animal for human consumption?

Milk can be taken immediately.

Why has Hiprabovis IBR Marker Live been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Hiprabovis IBR Marker Live exceed the risks for the active immunisation of cattle from three months of age against Bovine Herpes Virus type 1 to reduce the clinical signs of infectious bovine IBR and field

virus excretion and recommended that Hiprabovis IBR Marker Live be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Hiprabovis IBR Marker Live:

The European Commission granted a marketing authorisation valid throughout the European Union, for Hiprabovis IBR Marker Live to Laboratorios Hipra S.A. on 27 January 2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 27 January 2011.