12 November 2010
EMA/CVMP/257022/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[*]

Hiprabovis IBR Marker Live

Live marker vaccine to reduce clinical signs of infectious bovine rhinotracheitis (IBR) and field virus excretion.

On 10 November 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[**] recommending to grant a marketing authorisation for the veterinary medicinal for the product Hiprabovis IBR Marker Live, a lyophilisate and solvent for suspension for injection, intended for the active immunisation of cattle from 3 months of age against Bovine Herpes Virus type 1 (BoHV-1) to reduce the clinical signs of infectious bovine rhinotracheitis (IBR) and field virus excretion.

The applicant for this veterinary medicinal product is Laboratorios Hipra S.A.

The active substance of Hiprabovis IBR Marker Live is a live double-gene deleted (deleted glycoprotein E (gE^-) and deleted thymidine kinase (tk^-)) Bovine Herpes Virus type 1, strain.

The benefits of Hiprabovis IBR Marker Live is the stimulation of active immunity against bovine herpesvirus type 1 in cattle from 3 months of age reducing clinical signs of IBR and virus shedding. The onset of immunity is 21 days after completion of the basic vaccination scheme and the duration of immunity is 6 months after completion of the basic vaccination scheme.

The most common side effects are a slight increase in body temperature up to 1° C within 4 days following vaccination. Occasionally, an increase in rectal temperature up to 1.63º C in adult cows and up to 2.18º C in calves may be observed. This transient rise in temperature is spontaneously resolved within 48 hours without treatment and it is not related to a febrile process. A transient inflammation at the inoculation site is common in cattle within 72 hours post-vaccination. This slight swelling lasts for less than 24 hours in most cases.

[*] Summaries of opinion are published without prejudice to the Commission Decision.
[**] Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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The approved indication is:

" For the active immunisation of cattle from 3 months of age against Bovine Herpes Virus type 1 (BoHV-1) to reduce the clinical signs of infectious bovine rhinotracheitis (IBR) and field virus excretion.

Onset of immunity: 21 days after completion of the basic vaccination scheme.

Duration of immunity: 6 months after completion of the basic vaccination scheme."

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Hiprabovis IBR Marker Live and therefore recommends the granting of the marketing authorisation.