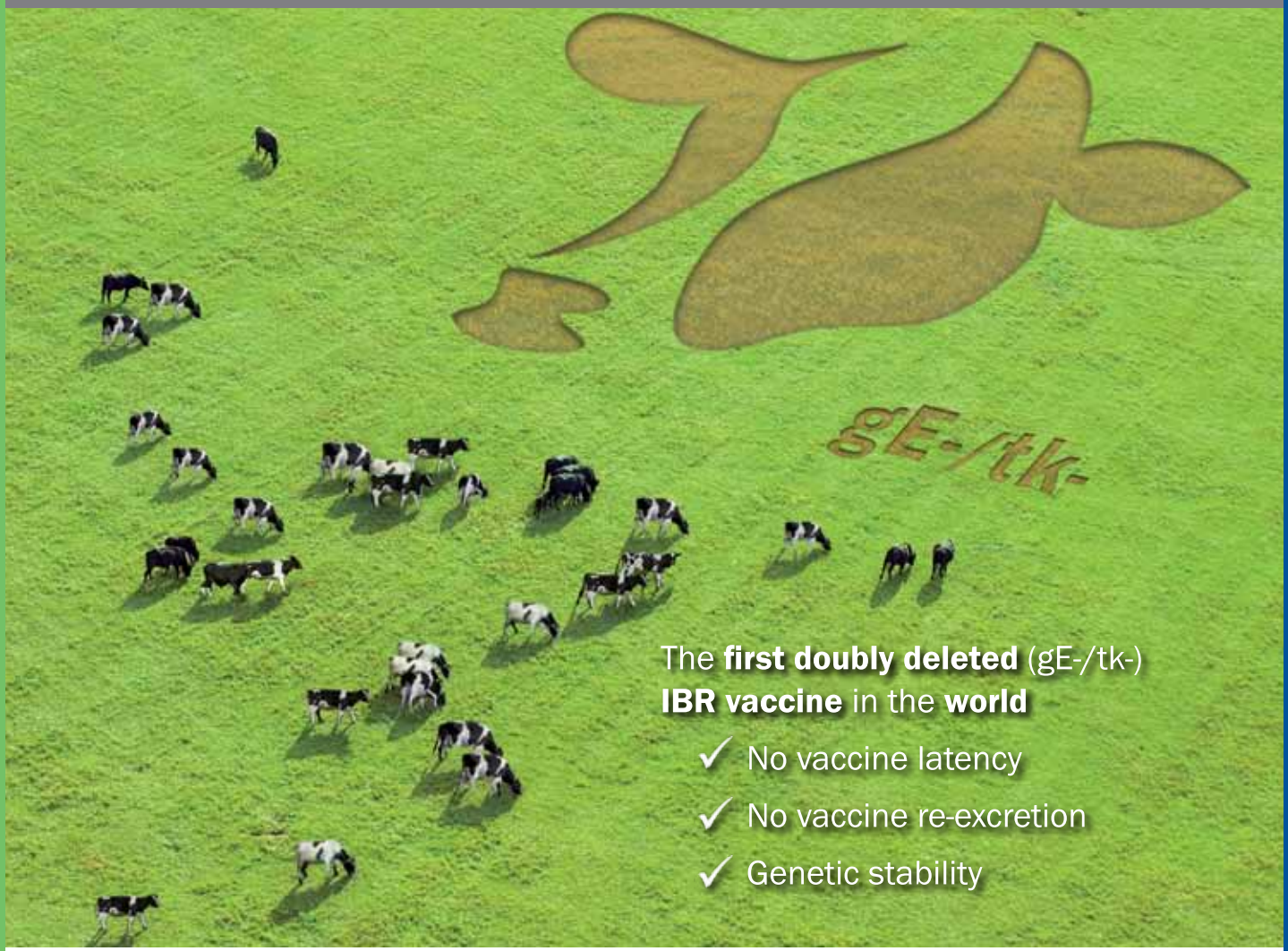
HIPRABOVIS® IBR MARKER LIVE

Doubly deleted gE-/tk- IBR live vaccine for cattle

MARKS A TREND



HIPRABOVIS® IBR MARKER LIVE Lyophilisate and solvent for suspension for injection for cattle. **Qualitative and quantitative composition: Each dose of 2 ml contains:** Lyophilisate: Live gE- tk- double-gene deleted Bovine Herpes Virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$. Solvent: Phosphate buffer solution. **Target species:** Cattle (calves and adult cows). **Indications for use, specifying the target species:** 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. **Special precautions for use in animals:** Vaccinate healthy animals only. **Adverse reactions (frequency and seriousness):** A slight increase in body temperature up to 1° C is common 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. Vaccination might exceptionally cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be administered. **Use during pregnancy or lactation:** Can be used during pregnancy and lactation. **Recommended vaccination programme:** Cattle: from the age of 3 months onwards. The recommended initial dose is 1 injection of 2 ml of the reconstituted vaccine per animal. The animal should be revaccinated 3 weeks later with the same dose. Thereafter a single booster dose of 2 ml should be administered every six months. The method of administration is by intramuscular route, in the neck muscles. Reconstitute the lyophilized tablet with the entire contents of the enclosed solvent to obtain a suspension for injection. The solvent should be allowed to warm to a temperature between 15 ºC to 20ºC before reconstitution of the lyophilised tablet. **Overdose (symptoms, emergency procedures, antidotes), if necessary:** No adverse reactions except those mentioned above were observed after the administration of a 10-fold vaccine dose. **Withdrawal period:** Zero days. **Incompatibilities:** Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product. **Shelf life:** Shelf life of the lyophilisate as packaged for sale: 2 years. Shelf life of the solvent as packaged for sale: 2 years. Shelf life after reconstitution: 6 hours. **Special precautions for storage:** Store and transport refrigerated (2° C - 8° C). Do not freeze. Keep the bottles in the outer carton in order to protect from light. **Marketing authorisation holder:** Laboratorios Hipra, S.A., Amer (Girona), SPAIN. **Legal Category:** ROI: POM . **Marketing authorisation numbers:** 5 doses: EU/2/10/114/001 ; 25 doses: EU/2/10/114/002. **Use medicines responsibly:** see www.noah.co.uk/responsible

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