SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivated suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Bovine herpes virus type 1 (BoHV-1), strain Difivac (gE-negative), to induce a GMT* of at least 1:160 in cattle.

*Geometric seroneutralising mean titre.

Adjuvants:

Aluminium hydroxide	14-24 mg
Quil A	0.25 mg

Excipients:

Thiomersal	0.2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pinkish liquid suspension, which might contain loose sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For active immunisation of cattle against Infectious Bovine Rhinotracheitis (IBR), to reduce the clinical signs and virus shedding and, in female cattle, to prevent abortions associated with BoHV-1 infection. The vaccination of pregnant cattle will prevent abortion associated with BoHV-1 infections as demonstrated during the second trimester of gestation upon challenge 28 days after vaccination.

Vaccinated cattle can be differentiated from field virus infected animals due to the marker deletion, unless the cattle were previously vaccinated with a conventional vaccine or infected with field virus.

Duration of immunity: 6 months.

Additional information on protection afforded by combined vaccination of Rispoval IBR-Marker Vivum* with Rispoval IBR-Marker Inactivatum: for booster immunisation after primary vaccination with Rispoval IBR-Marker Vivum* to reduce the virus shedding and the clinical signs associated with BoHV-1 infection in cattle and, in female cattle, to prevent abortions associated with BoHV-1 infection. This vaccination of cattle will prevent abortion associated with BoHV-1 infections as demonstrated during the third trimester of gestation upon challenge 86 days after the booster vaccination.

Duration of immunity: 6 months after complete primary vaccination with Rispoval IBR-Marker Vivum* followed by 12 months after annual booster with Rispoval IBR-Marker Inactivatum.
In order to prevent abortion in female cattle that have received basic immunisation, a single dose revaccination with Rispoval IBR-Marker Inactivatum is recommended to be applied no later than by the start of the second trimester of each further pregnancy.

* Where this veterinary medicinal product is authorised.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1], Allergic reaction[2]

[1]Transient subcutaneous, up to 5 cm, which subsides within 14 days.
[2]Vaccinated animals should be observed for approximately 30 minutes following immunisation. If such reactions occur, antiallergics should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Immunosuppressive substances, i.e. corticosteroids or Bovine Virus Diarrhoea modified live vaccines, should be avoided in a period of 7 days prior to and after vaccination as this may impair the development of the immunity.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amount(s) to be administered and administration route

Posology:
The dose of vaccine is 2 ml for cattle over 3 months of age, for subcutaneous use. The vaccination scheme consists of basic immunisation and booster vaccinations.

Basic immunisation:

Cattle at 3 months of age or older at first vaccination
Two doses, each of 2 ml, 3-5 weeks apart.

Booster vaccinations:

Booster vaccinations of cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Inactivatum:
One dose of 2 ml at 6 month intervals.

Booster Vaccinations of cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Vivum:*
Cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Vivum* (according to the product information for this veterinary medicinal product) may be given booster vaccinations with Rispoval IBR-Marker Inactivatum. These animals should be given a single dose booster vaccination with Rispoval IBR-Marker Inactivatum 6 months after their initial vaccination course with Rispoval IBR-Marker Vivum*. Thereafter, single dose booster vaccinations with Rispoval IBR-Marker Inactivatum should be administered every 12 months.

If calves under the age of 3 months should be vaccinated the development of immunity may be impaired by maternal antibodies. These calves should be revaccinated when they are over 3 months of age.

It is recommended to vaccinate all cattle of a herd.

For female cattle for protection against abortion:
To prevent abortions associated with BoHV-1 female cattle require a primary course of two subcutaneous doses of vaccine 3-5 weeks apart, or alternatively a primary course of a single intramuscular dose of Rispoval IBR-Marker Vivum* followed 6 months later by a single dose booster using Rispoval IBR-Marker Inactivatum. In order to cover the main abortion risk period, it is recommended that the second dose of the primary course of two subcutaneous doses or the single dose booster using Rispoval IBR-Marker Inactivatum is administered no later than by the start of the second trimester of each pregnancy.

Method of administration:

Shake the vaccine well before use. Use only sterile needles and syringes for administration. Avoid the introduction of contamination during use. The liquid suspension is injected aseptically via the subcutaneous route.

Vaccination schemes summary:

From 2 weeks to 3 months of age

Rispoval IBR-Marker vaccine used			
Primary Vaccination		**Revaccination Intervals**	
First dose (vaccine, route of administration)	**Second dose (vaccine, route of administration)**	**Interval to next booster vaccination (vaccine, route of administration)**	**All subsequent booster vaccinations (vaccine, route of administration)**
2 weeks (Vivum*, intranasal)	3 months (Vivum*, intramuscular)	6 months (Vivum*, intramuscular)	6 months (Vivum*, intramuscular)
2 weeks (Vivum*, intranasal)	3 months (Vivum**,** intramuscular)	6 months (Inactivatum, subcutaneous)	12 months (Inactivatum, subcutaneous)

From 3 months of age

Rispoval IBR-Marker vaccine used		
Primary Vaccination (number of doses, route of administration)	**Revaccination Intervals**	
	Interval to first booster vaccination (vaccine, route of administration)	**All subsequent booster vaccinations (vaccine, route of administration)**
Vivum* (one dose, intramuscular or intranasal)	6 months (Vivum*, intramuscular)	6 months (Vivum*, intramuscular)
Vivum* (one dose, intramuscular)	6 months (Inactivatum, subcutaneous)	12 months (Inactivatum, subcutaneous)
Inactivatum (two doses, subcutaneous, with 3-5 week interval)	6 months (Inactivatum, subcutaneous)	6 months (Inactivatum, subcutaneous)

For female cattle for protection against abortion

Rispoval IBR-Marker vaccine used	
Primary Vaccination (number of doses, route of administration) recommended to be applied no later than by the start of second trimester of pregnancy	**Revaccination**
Vivum* (two doses, intramuscular, with 3-5 weeks interval)	Inactivatum (one dose, subcutaneous) recommended to be applied no later than by the start of the second trimester of each pregnancy
Vivum* (one dose, intramuscular) followed by Inactivatum (one dose, subcutaneous), with 6 months interval	
Inactivatum (two doses, subcutaneous, with 3-5 week interval)	

For vaccination in known high BoHV-1 infection pressure

Rispoval IBR-Marker vaccine used		
Primary Vaccination (number of doses, route of administration)	**Revaccination Intervals**	
	Interval to first booster vaccination (vaccine, route of administration)	**All subsequent booster vaccinations (vaccine, route of administration)**
Vivum* (one dose, intranasal), followed by Vivum* (one dose, intramuscular) with 3-5 weeks interval	6 months (Vivum*, intramuscular, OR Inactivatum, subcutaneous)	6 months (Vivum*, intramuscular) OR 12 months (Inactivatum, subcutaneous)

* Where this veterinary medicinal product is authorised.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned in section 4.6 “Adverse reactions (frequency and seriousness)” were observed after administration of a double dose of the vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccine.

ATCvet code: QI02AA03

Glycoprotein gE is absent in virus particles of Rispoval IBR-Marker Inactivatum. Therefore the vaccine virus, and the antibodies against it can be clearly differentiated from field strains, or antibodies against the latter by serological methods, unless the cattle were previously vaccinated with a conventional vaccine or infected with field virus.

The vaccine induces immunity in cattle against clinical respiratory symptoms caused by Bovine herpes virus. Following infection the intensity and duration of clinical symptoms as well as the titre and duration of virus shedding are significantly reduced. As with other vaccines, vaccination may not completely prevent but does reduce risk of infection. The veterinary medicinal product induces antibodies in vaccinated cattle, which are detected in the serum neutralisation test and in conventional ELISA tests. With specific test kits these antibodies can be differentiated - due to the lack of antibodies against gE - from those of field virus infected animals or animals vaccinated with conventional vaccines.

Vaccination of all cattle in a herd, both infected and uninfected, is recommended. Following use of Rispoval IBR-Marker Inactivatum the risk of infection, titre and duration of virus shedding are all reduced. The duration of a programme to achieve the status of a BoHV-1 free herd is dependent on the initial level of BoHV-1 infection in the herd and the culling of remaining BoHV-1 positive animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Phenolsulfonphthalein
HEPES-Na
Sodium thiosulfate
Minimum Essential Medium

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 8 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Multidose containers:

10 doses: 1 glass vial with 20 ml (10 doses) inactivated vaccine, closed with bromobutyl rubber stoppers and sealed with an aluminium ring with a flip-off cap, packed as 1 vial in a folding carton.

50 doses: 1 glass vial with 100 ml (50 doses) inactivated vaccine, closed with bromobutyl rubber stoppers and sealed with an aluminium ring with a flip-off cap, packed as 1 vial in a folding carton.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5141

9. DATE OF FIRST AUTHORISATION

05 February 1999

10. DATE OF REVISION OF THE TEXT

August 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 13 August 2024
Gavin Hall