1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivatum, suspension for injection for cattle

Rispoval IBR-Marker Inactivated *(for UK and Ireland only)*
Rispoval IBR-Marker *(for France only)*
Rispoval Marker Inattivato *(for Italy only)*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substance:
Bovine Herpes Virus type 1 (BoHV-1), strain Difivac (gE-negative), to induce a geometric mean seroneutralizing titre of at least 1:160 in cattle.

Adjuvant(s):

Aluminium hydroxide	14-24 mg
Quil A	0.25 mg

Excipient(s):

Preservative	
Thiomersal	0.2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

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

- For booster immunisation after primovaccination with Rispoval IBR-Marker Vivum (in member states where this product is authorized) 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 primovaccination with Rispoval IBR-Marker Vivum followed by 12 month 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.

4.3 Contraindications

Do not use in unhealthy animals.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
None.

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.

4.6 Adverse reactions (frequency and seriousness)

Transient subcutaneous swelling up to 5 cm in diameter, which subsides within 14 days, may occur at the injection site in very rare cases. In very rare cases allergic reactions may occur as with other vaccines, therefore vaccinates should be observed for approximately 30 minutes following immunisation. In those cases, antiallergics should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Posology

The dose of vaccine is 2 ml for cattle over 3 months of age, for subcutaneous injection.

The vaccination scheme consists of basic immunisation and booster vaccinations.

Basic immunisation:
Two injections of 1 dose (2 ml) each 3-5 weeks apart.

Booster vaccinations of cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Inactivatum:
1 dose (2 ml) 6 months apart.

Booster Vaccinations of cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Vivum (in member states where this product is authorized):
Cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Vivum (according to the product information for this 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.

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. 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		Revaccination intervals	
Primary vaccination			
First dose, from 2 weeks of age (route of administration)	Second dose, at 3 months of age (route of administration)	Interval to next booster vaccination (vaccine and route of administration)	All subsequent booster vaccinations (vaccine and route of administration)
Vivum (intranasal)	Vivum (intramuscular)	6 months (Vivum, intramuscular)	6 months (Vivum, intramuscular)
Vivum (intranasal)	Vivum (intramuscular)	6 months (Inactivatum, subcutaneous)	12 months (Inactivatum, subcutaneous)

From 3 months of age

Rispoval IBR-Marker vaccine used	Revaccination intervals	
Primary vaccination (number of doses and route of administration)	Interval to first booster vaccination (vaccine and route of administration)	All subsequent booster vaccinations (vaccine and route of administration)
Vivum (one dose, intramuscular)	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	Revaccination
Vaccination schedule (number of doses and route of administration) recommended to be applied no later than by the start of second trimester of pregnancy	
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	Revaccination intervals	
Primary vaccination (number of doses and route of administration)	**Interval to first booster vaccination (vaccine and route of administration)**	**All subsequent booster vaccinations (vaccine and 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)**

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

Reactions after administration of a double dose of vaccine are not different from those after the single dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Inactivated viral vaccine.
ATCvet code: QI02AA03

The vaccine induces immunity in cattle against clinical respiratory symptoms caused by the Infectious Bovine Rhinotracheitis (IBR) 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 product induces in vaccinated cattle antibodies, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenolsulfonphthalein
HEPES-Na
Sodium thiosulfate
Thiomersal
Minimum Essential Medium

6.2 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: 36 months
Shelf-life after first opening the immediate packaging: 8 hours

6.4 Special precautions for storage

Store in a refrigerator (+2°C to +8°C). Protect from frost, heat or 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

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

To be completed nationally.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF RENEWAL OF THE AUTHORISATION

To be completed nationally.

10 DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.