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 mean seroneutralising titre.

Adjuvants:

Aluminium hydroxide	14-24 mg
Quil A	0.25 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Phenolsulfonphthalein	
HEPES-Na	
Sodium thiosulfate	
Minimum Essential Medium	

Pinkish liquid suspension, which might contain loose sediment.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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 Live* with Rispoval IBR-Marker Inactivated: for booster immunisation after primary vaccination with Rispoval IBR-Marker Live* 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 Live* followed by 12 months after annual booster with Rispoval IBR-Marker Inactivated.
In order to prevent abortion in female cattle that have received basic immunisation, a single dose revaccination with Rispoval IBR-Marker Inactivated 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

3.6 Adverse events

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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 Inactivated:
One dose of 2 ml at 6 month intervals.

Booster Vaccinations of cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Live:*
Cattle having been administered the primary vaccination scheme using Rispoval IBR-Marker Live* (according to the product information for this veterinary medicinal product) may be given booster vaccinations with Rispoval IBR-Marker Inactivated. These animals should be given a single dose booster vaccination with Rispoval IBR-Marker Inactivated 6 months after their initial vaccination course with Rispoval IBR-Marker Live*. Thereafter, single dose booster vaccinations with Rispoval IBR-Marker Inactivated 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 Live* followed 6 months later by a single dose booster using Rispoval IBR-Marker Inactivated. 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 Inactivated 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 (Live*, intranasal)	3 months (Live*, intramuscular)	6 months (Live*, intramuscular)	6 months (Live*, intramuscular)
2 weeks (Live*, intranasal)	3 months (Live**,** intramuscular)	6 months (Inactivated, subcutaneous)	12 months (Inactivated, 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)**
Live* (one dose, intramuscular or intranasal)	6 months (Live*, intramuscular)	6 months (Live*, intramuscular)
Live* (one dose, intramuscular)	6 months (Inactivated, subcutaneous)	12 months (Inactivated, subcutaneous)
Inactivated (two doses, subcutaneous, with 3-5 week interval)	6 months (Inactivated, subcutaneous)	6 months (Inactivated, 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**
Live* (two doses, intramuscular, with 3-5 weeks interval)	Inactivated (one dose, subcutaneous) recommended to be applied no later than by the start of the second trimester of each pregnancy
Live* (one dose, intramuscular) followed by Inactivated (one dose, subcutaneous), with 6 months interval	
Inactivated (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)**
Live* (one dose, intranasal), followed by Live* (one dose, intramuscular) with 3-5 weeks interval	6 months (Live*, intramuscular, OR Inactivated, subcutaneous)	6 months (Live*, intramuscular) OR 12 months (Inactivated, subcutaneous)

* Where this veterinary medicinal product is authorised.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 “Adverse events” were observed after administration of a double dose of the vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICALINFORMATION

4.1 ATCvet code: QI02AA03

Glycoprotein gE is absent in virus particles of Rispoval IBR-Marker Inactivated. 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 (BoHV-1). 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 IBR vaccines.

Vaccination of all cattle in a herd, both infected and uninfected, is recommended. Following use of Rispoval IBR-Marker Inactivated 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/061/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/03/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).