# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**
1x20 ml (10 doses), 1x100 ml (50 doses)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivatum
Suspension for injection for cattle.

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2 ml) contains:
BoHV-1, strain Difivac (gE-negative) to induce a GMT of at least 1:160 in cattle
Aluminium hydroxide
Quil A
Thiomersal

## 3. PHARMACEUTICAL FORM

Suspension for injection

## 4. PACKAGE SIZE

1 x 20 ml (10 doses)
1 x 100 ml (50 doses)

## 5. TARGET SPECIES

Cattle

## 6. INDICATION(S)

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.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**Dose**: 2 ml for cattle over 3 months of age.
**Route**: Subcutaneous injection
**Vaccination programme**: Two injections 3-5 weeks apart. Booster vaccination every 6-12 months (depending on vaccine used for primary vaccination).
Shake well before use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Zero days

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

Expiry date:
Once opened use within 8 hours.

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (+2°C to +8°C). Protect from heat and light. Do not freeze.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4127

## 17. MANUFACTURER'S BATCH NUMBER

Lot No.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL ON GLASS VIAL**
20 ml (10 doses)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivatum
Suspension for injection for cattle

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (2 ml) contains:
BoHV-1, strain Difivac (gE-negative) to induce a GMT of at least 1:160 in cattle

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml (10 doses)

## 4. ROUTE(S) OF ADMINISTRATION

For subcutaneous injection.

## 5. WITHDRAWAL PERIOD

Zero days

## 6. BATCH NUMBER

Lot No.

## 7. EXPIRY DATE

Expiry date:
Once opened use within 8 hours.

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL ON GLASS VIAL**
100 ml (50 doses)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivatum
Suspension for injection for cattle

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2 ml) contains:
BoHV-1, strain Difivac (gE-negative) to induce a GMT of at least 1:160 in cattle
Aluminium hydroxide
Quil A
Thiomersal

## 3. PHARMACEUTICAL FORM

Suspension for injection

## 4. PACKAGE SIZE

100 ml (50 doses)

## 5. TARGET SPECIES

Cattle

## 6. INDICATION(S)

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.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**Dose:** 2 ml for cattle over 3 months of age.
**Route:** Subcutaneous injection.
Shake well before use.
Read package leaflet before use.

## 8. WITHDRAWAL PERIOD

Zero days

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

Expiry date:
Once opened use within 8 hours.

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (+2°C to +8°C). Protect from heat and light. Do not freeze.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4127

## 17. MANUFACTURER'S BATCH NUMBER

Lot No.:

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET
# Rispoval IBR-Marker Inactivatum
# Suspension for injection for cattle

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

**Marketing authorisation holder:**
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

**Manufacturer for the batch release:**
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval IBR-Marker Inactivatum
Suspension for injection for cattle.

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose (2 ml) 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.

**Adjuvant(s)**

| | |
|---|---|
| Aluminium hydroxide | 14-24 mg |
| Quil A | 0.25 mg |

**Excipient(s):**

| | |
|---|---|
| Thiomersal | 0.2 mg |

Pinkish liquid suspension, which might contain loose sediment.

## 4. INDICATION(S)

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.

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 month 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 revacination with Rispoval IBR-Marker Inactivatum is recommended to be applied no later than by the start of the second trimester of each further pregnancy.

## 5. CONTRAINDICATIONS

Do not use in unhealthy animals.

## 6. ADVERSE REACTIONS

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 vaccinated animals should be observed for approximately 30 minutes following immunisation. In such cases, antiallergics should be administered.

If you notice any serious effects or other not mentioned in this leaflet, please inform your veterinary surgeon.

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).

## 7. TARGET SPECIES

Cattle

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

**Dose:** 2 ml for cattle over 3 months of age.
**Route:** Subcutaneous injection.

**Vaccination scheme:**
The vaccination scheme consists of basic immunisation and booster vaccinations.
*Basic immunisation:* Two doses, each of 2 ml, 3-5 weeks apart.

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

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.

It is recommended that all cattle in the herd receive vaccination.

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.

Shake the vaccine well before use. Use only sterile needles and syringes for administration. Avoid the introduction of contamination during use.

Due to the presence of maternal antibodies, the development of immunity in calves under 3 months of age may be impaired. These animals should be revaccinated when they are over 3 months of age.

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)** |

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (+ 2°C to + 8°C). Protect from heat and light. Do not freeze. Do not use after the expiry date which is stated on the label.
Shelf life after first opening the container: 8 hours

## 12. SPECIAL WARNING(S)

For animal treatment only.
To be supplied only on veterinary prescription.

Can be used during pregnancy and lactation.

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.

Do not mix with any other veterinary medicinal product.

Reactions after administration of an overdose of vaccine are not different from those after the single dose.

**Special precautions to be taken by the user:**
In case of accidental self injection, seek medical advice immediately and show the package leaflet or label to the physician.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2019

## 15. OTHER INFORMATION

**Rispoval IBR-Marker Inactivatum** can be used during pregnancy and lactation.

Glyoprotein 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 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 antibodies in vaccinated cattle, which are detected in the serum neutralising test and in conventional ELISA tests. With specific gE test kits these antibodies can be differentiated 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 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.

Pack Size:
1 x 20 ml (10 doses)
1 x 100 ml (50 doses)

Not all pack sizes may be marketed

For any information about this veterinary medicinal product please contact the local representative of the marketing authorisation holder.

Approved 14 November 2019