ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 x 25 (50 ml) doses
Cardboard box containing 4 x 25 (50 ml) doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CattleMarker IBR Inactivated
Emulsion for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 2 ml dose contains:
Inactivated gE - BoHV-1, strain Difivac, to induce a geometric mean seroneutralizing titre ≥5.5 $\log_2$
Procision-A: 0.164 ml
Thiomersal: max 0.2 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1 x 25 doses
4 x 25 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial before use.
For subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4190

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 x 5 (10 ml) doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CattleMarker IBR Inactivated
Emulsion for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 2 ml dose contains:
Inactivated gE - BoHV-1, strain Difivac, to induce a geometric mean seroneutralizing titre ≥5.5 $\log_2$
Procision-A: 0.164 ml
Thiomersal: max 0.2 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1 x 5 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial before use.
For subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4190

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Colourless Type I Glass Vial – 25 (50 ml) doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CattleMarker IBR Inactivated
Emulsion for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 2 ml dose contains:
Inactivated gE - BoHV-1, strain Difivac, to induce a geometric mean seroneutralizing titre ≥5.5 $\log_2$

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

25 doses

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Colourless Type I Glass Vial – 5 (10 ml) doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CattleMarker IBR Inactivated
Emulsion for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 2 ml dose contains:
Inactivated gE - BoHV-1, strain Difivac, to induce a geometric mean seroneutralizing titre ≥5.5 $\log_2$

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

5 doses

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CattleMarker IBR Inactivated
Emulsion 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 and manufacturer responsible for batch release:
Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CattleMarker IBR Inactivated
emulsion for injection for cattle

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

Each 2 ml dose contains the following:

Active substance:

Inactivated gE negative Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralizing titre of at least 5.5 $\log_2$

Adjuvant:

Procision A™: 0.164 ml/dose of vaccine
Composition of the adjuvant (per ml)
- Quil A: 3.05 mg
- Cholesterol: 3.05 mg
- Amphigen Base (liquid paraffin + soya lecithin): 0.076 ml
- Drakeol 5 (liquid paraffin): 0.228 ml.

Excipients
Thiomersal max 0.2mg

4. INDICATION(S)

For active immunisation of seronegative cattle from 2 weeks of age:

- to reduce the clinical signs (pyrexia and depression) of infectious bovine rhinotracheitis (IBR) and duration of virus shedding caused by BoHV-1 infection.

  Onset of protection: 2 weeks after completion of the primary vaccination course.

  Duration of protection: 6 months after completion of the primary vaccination course

For active immunisation of female cattle from 6 months of age:

- to reduce the clinical signs (pyrexia and duration of dyspnoea) of infectious bovine rhinotracheitis (IBR) and virus shedding caused by BoHV-1 infection.

  Onset of protection: 2 weeks after completion of the primary vaccination course.
  Duration of protection: 12 months after completion of the primary vaccination course.
- to reduce the incidence of abortions associated with BoHV-1 infections as demonstrated during the second trimester of gestation following challenge.

Onset of protection: completion of the primary course of vaccination at least 19 days prior to breeding or insemination affords protection during the period of risk of transplacental infection by BoHV-1. Period of risk of BoHV-1 transplacental infection leading to abortion starts around the beginning of 5th month of pregnancy.

Duration of protection: 12 months protection after the primary vaccination course as demonstrated by challenge.

5. CONTRAINDICATIONS

Do not mix with any other veterinary medicinal product.

6. ADVERSE REACTIONS

Calves from 2 weeks of age:

Administration of the vaccine may be followed very commonly by a transient pyrexia lasting for a maximum of 4 days which may commonly be associated with slight depression for 2 days.

Animals will very commonly show detectable swellings to a maximum of 12.8 cm diameter which may be warm, firm and sensitive to palpation. These usually resolve within 14 days exceptionally 27 days. In repeated dosing studies when an additional third dose was given shortly after the recommended two dose primary vaccination course, increased magnitude injection site reactions were seen. As part of the immune reaction following vaccination, inflammatory cell infiltration and/or fibrosis may occur in the dermal tissue at the injection site.

Animals from 6 months of age:

Administration of the vaccine may be followed very commonly by a mild, transient pyrexia lasting for a maximum of 4 days and which is not associated with any clinical illness or significant reduction in milk production.

Animals will very commonly show detectable swellings to a maximum of 40 cm diameter which may be warm, firm and sensitive to palpation. These usually resolve within 14 days exceptionally 43 days. In repeated dosing studies when an additional third dose was given shortly after the recommended two dose primary vaccination course, increased magnitude injection site reactions were seen and a temperature rise of 3°C can be rarely observed lasting 1 day. As part of the immune reaction following vaccination, inflammatory cell infiltration and/or fibrosis may occur in the dermal tissue at the injection site lasting for at least 14 days.
Administration of the vaccine during pregnancy may be followed very commonly by swellings to a maximum of 23 cm diameter lasting for 3 weeks or longer. A mild transient reduction in daily milk yield may very commonly occur for up to two days after vaccination.

Anaphylactic type reactions may occur uncommonly resulting in transient clinical signs such as tachycardia or hyperpnoea. These clinical signs normally resolve without treatment. In case of severe reactions, appropriate treatment is recommended.

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).

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

7. TARGET SPECIES

Cattle.

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

For subcutaneous use.

Primary vaccination:
Administer two doses of 2 ml three weeks apart:

For cattle from 2 weeks of age:

Completion of primary course of vaccination at least 2 weeks before exposure to BoHV-1, affords protection against clinical signs of IBR and duration of virus shedding as described in section 4.

Booster vaccination:
Administer a single dose of 2 ml every 6 months or alternatively, when cattle are older than 6 months, administer two doses of 2 ml three weeks apart followed by single dose boosters of 2 ml every 12 months..

For female cattle from 6 months of age:
Completion of primary course of vaccination at least 2 weeks before exposure to BoHV-1, affords protection against clinical signs of IBR and virus shedding as described in section 4.2.
Completion of primary course of vaccination at least 19 days prior to breeding or insemination affords protection during the period of risk of transplacental infection by BoHV-1.

Booster vaccination:
Administer a single dose of 2 ml every 12 months. Booster vaccinations may be administered before or during pregnancy. In order to cover the main abortion risk period, it is recommended that single dose booster is administered no later than by the start of the second trimester of pregnancy.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial before use.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C). Do not freeze. A slight black deposit may appear during storage.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Once broached, use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Do not vaccinate unhealthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product seek prompt medical advice even if only a very small amount is injected and take the package insert with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered to animals from 6 months of age and older on the same day but not mixed with Spirovac; no impairment of the serological response to the Leptospira and BoHV-1 components was observed, but efficacy was not established by challenge for these 2 components and cell mediated immunity to Leptospira was not investigated.

Concurrent vaccination with CattleMarker IBR inactivated and Spirovac may increase the severity and duration of the local reaction to Spirovac (the maximum size of the injection site reaction observed was 24 cm, and in some cases the reaction may persist up to 70 days post-vaccination, or longer).

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

Overdose (symptoms, emergency procedures, antidotes):

Administration of a double dose of the vaccine shortly before breeding or during pregnancy may be followed commonly by slight depression and very commonly by swellings to a maximum of 23 cm diameter lasting for 3 weeks or longer. During the 3rd trimester of pregnancy, swellings may persist for up to 63 days.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

Use during pregnancy and lactation:

Can be used during pregnancy and lactation.

Can be used concurrently with Spirovac during the first and second trimesters of pregnancy and during lactation.

The presence of maternal antibodies at the time of vaccination has been shown to interfere with the protection against IBR.
Young calves may have maternally derived antibodies to BoHV-1, which have been shown to affect the immune response to vaccination.
In the presence of maternal antibodies, timing of initial vaccination of calves should be planned accordingly.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<TBD>

15. OTHER INFORMATION

CattleMarker IBR inactivated is available in colourless Type I glass vials containing 5 (10 ml) or 25 (50 ml) doses in the following pack sizes:

Cardboard box of 1 vial of 5 doses (10 ml),
Cardboard box of 1 vial of 25 doses (50 ml)
Cardboard box of 4 vials of 25 doses (50 ml).

Not all package sizes may be marketed.

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

Approved: 21/07/2016