ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS IBR MARKER LIVE lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:
Live gE^- tk^- double-gene deleted bovine herpes virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$.

Abbreviations:
gE^-: deleted glycoprotein E; tk^-: deleted thymidine kinase; CCID: cell culture infectious dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatine
Monosodium glutamate
Sodium chloride
Potassium chloride
Sucrose
Water for injections
Solvent:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

Lyophilisate: white to yellowish powder.
Solvent: transparent homogenous liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves and adult cows).

3.2 Indications for use for each target species

For the active immunisation of cattle from 3 months of age against bovine herpes virus type 1 (BoHV-1) to reduce the clinical signs of Infectious bovine rhinotracheitis (IBR) and field virus excretion.

Onset of immunity: 21 days after completion of the basic vaccination scheme.
Duration of immunity: 6 months after completion of the basic vaccination scheme.

3.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves and adult cows):

Common (1 to 10 animals / 100 animals treated):	Elevated temperature[1]. Injection site inflammation[2].
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction[3].

[1]A slight increase in body temperature up to 1 °C within 4 days following vaccination. An increase in rectal temperature up to 1.63 ºC in adult cows and up to 2.18 ºC in calves may be observed. This transient rise in temperature is spontaneously resolved within 48 hours without treatment and it is not related to a febrile process.
[2]A transient inflammation at the inoculation site in cattle within 72 hours post-vaccination. This slight swelling lasts for less than 24 hours in most cases.
[3]Including anaphylaxis (sometimes fatal). In such cases, an appropriate symptomatic treatment 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

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

Cattle: from the age of 3 months onwards.

Administer one dose of 2 ml by intramuscular injection in the neck muscles.

Reconstitute the lyophilisate with the entire contents of the supplied solvent to obtain a suspension for injection. A transparent pinkish liquid is obtained after reconstitution.

Recommended vaccination programme:
The recommended initial dose is 1 injection of 2 ml of the reconstituted vaccine per animal. The animal should be revaccinated 3 weeks later with the same dose.
Thereafter a single booster dose of 2 ml should be administered every six months.

The method of administration is by intramuscular route, in the neck muscles. The injections should be preferably administered on the alternate sides of the neck. The solvent should be allowed to warm to a temperature between 15 ºC and 20 ºC before reconstitution of the lyophilisate. Shake well before use. Avoid the introduction of contamination during reconstitution and use. Use only sterile needles and syringes for administration.

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

No adverse reactions except those mentioned in section 3.6 were observed after the administration of a 10 - fold vaccine dose.

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

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AD01.

To stimulate active immunity against bovine herpesvirus type 1 (BoHV-1) in cattle. The vaccine contains a BoHV-1 strain (CEDDEL strain) that is double deleted within the genes coding for the gE surface protein and the tk enzyme. The tk deletion is related to reduced viral neurotropism and reduced establishment of latency. The absence of the gene coding for the gE surface protein entails that the

vaccine does not elicit antibodies to glycoprotein E of BoHV-1 (marker vaccine). This enables discrimination between cattle vaccinated with this vaccine and cattle infected with BoHV-1 field virus or vaccinated with conventional non-marker BoHV-1 vaccines. Diagnostic tools designed to detect gE antibodies should be suitable for this purpose. Animals exposed to gE surface protein will test positive (i.e. cattle infected with BoHV-1 field virus or vaccinated with conventional non-marker BoHV-1 vaccines) but unexposed animals will test negative (i.e. non-infected animals, including those vaccinated with HIPRABOVIS IBR MARKER LIVE). Animals vaccinated with HIPRABOVIS IBR MARKER LIVE will test positive (alongside cattle infected with BoHV-1 field virus or vaccinated with conventional non-marker BoHV-1 vaccines) when samples are analysed in tests based on the identification of antibodies to any other BoHV-1 antigens.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 5 years.
Shelf life after reconstitution according to directions: 6 hours.

5.3 Special precautions for storage

Lyophilisate: Store and transport refrigerated (2 °C – 8 °C).
Solvent of 5 and 25 doses: Store and transport refrigerated (2 °C – 8 °C).
Solvent of 30 doses: Do not store and transport above 25 ºC.
Do not freeze.
Keep the bottles in the box in order to protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate: Colourless type I glass bottle closed with a bromobutyl rubber closure and an aluminium cap.

Solvent: Colourless type I glass bottle (10 ml) or type II glass bottle (50 ml, or 100 ml containing 60 ml of solvent) or PET bottles (10, 50,or 100 ml containing 60 ml of solvent) closed with a bromobutyl rubber closure and an aluminium cap.

Package sizes:
Cardboard box containing 1 bottle with 5 doses of lyophilisate and 1 bottle with 10 ml of solvent.
Cardboard box containing 1 bottle with 25 doses lyophilisate and 1 bottle with 50 ml of solvent.
Cardboard box containing 1 bottle with 30 doses of lyophilisate.
Cardboard box containing 1 bottle with 60 ml of solvent.

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

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/114/001
EU/2/10/114/002
EU/2/10/114/003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/01/2011

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX: 5 AND 25 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS IBR MARKER LIVE lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml: Live gE^- tk^- double-gene deleted bovine herpes virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$.

3. PACKAGE SIZE

5 doses
25 doses

4. TARGET SPECIES

Cattle (calves and adult cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted, use by 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/114/001 5 doses
EU/2/10/114/002 25 doses

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX: 30 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS IBR MARKER LIVE lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml: Live gE^- tk^- double-gene deleted bovine herpes virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$.

3. PACKAGE SIZE

30 doses

4. TARGET SPECIES

Cattle (calves and adult cows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted, use by 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/114/003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX: 30 DOSES SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for HIPRABOVIS IBR MARKER LIVE

2. STATEMENT OF ACTIVE SUBSTANCES

Phosphate buffer solution.

3. PACKAGE SIZE

60 ml

4. TARGET SPECIES

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store and transport above 25 C.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE FOR THE LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS IBR MARKER LIVE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 2 ml: Live gE^- tk^- double-gene deleted bovine herpes virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

5 doses
25 doses
30 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE FOR THE SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for HIPRABOVIS IBR MARKER LIVE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. PACKAGE SIZE

10 ml
50 ml
60 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

HIPRABOVIS IBR MARKER LIVE lyophilisate and solvent for suspension for injection for cattle

2. Composition

Lyophilisate:
Each dose of 2 ml contains: Live gE^- tk^- double-gene deleted bovine herpes virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3}$ – $10^{7.3}$ $CCID_{50}$.

Abbreviations:
gE^-: deleted glycoprotein E; tk^-: deleted thymidine kinase; CCID: cell culture infectious dose

Lyophilisate: white to yellowish powder.
Solvent: transparent homogenous liquid.

3. Target species

Cattle (calves and adult cows).

4. Indications for use

For the active immunisation of cattle from 3 months of age against bovine herpes virus type 1 (BoHV-1) to reduce the clinical signs of Infectious bovine rhinotracheitis (IBR) and field virus excretion.

Vaccinated animals can be differentiated from field virus infected animals due to the marker deletion (gE^-) by means of commercial diagnostic kits, unless the animals were previously vaccinated with a conventional vaccine or infected with field virus.

Onset of immunity: 21 days after completion of the basic vaccination scheme.
Duration of immunity: 6 months after completion of the basic vaccination.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release is required for this product.

Special precautions for safe use in the target species:
Not applicable.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose:
No adverse reactions except those mentioned in section 6 "Adverse reactions" were observed after the administration of a 10-fold vaccine dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

7. Adverse events

Cattle (calves and adult cows):

Common (1 to 10 animals / 100 animals treated):
Elevated temperature[1]. Injection site inflammation[2].
Rare (1 to 10 animals / 10 000 animals treated):
Hypersensitivity reaction[3].

[1]A slight increase in body temperature up to 1 °C within 4 days following vaccination. An increase in rectal temperature up to 1.63 ºC in adult cows and up to 2.18 ºC in calves may be observed. This transient rise in temperature is spontaneously resolved within 48 hours without treatment and it is not related to a febrile process.
[2]A transient inflammation at the inoculation site in cattle within 72 hours post-vaccination. This slight swelling lasts for less than 24 hours in most cases.
[3]Including anaphylaxis (sometimes fatal). In such cases, an appropriate symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Cattle from the age of 3 months onwards.
Administer one dose of 2 ml by intramuscular injection in the neck muscles.

9. Advice on correct administration

Reconstitute the lyophilisate with the entire contents of the supplied solvent to obtain a suspension for injection. A transparent pinkish liquid is obtained after reconstitution.

Recommended vaccination programme:

The recommended initial dose is 1 injection of 2 ml of the reconstituted vaccine per animal. The animal should be revaccinated 3 weeks later with the same dose. Thereafter a single booster dose of 2 ml should be administered every six months.

The method of administration is by intramuscular route, in the neck muscles. The injections should be preferably administered on the alternate sides of the neck. The solvent should be allowed to warm to a temperature between 15 and 20 ºC before reconstitution of the lyophilisate. Shake well before use. Avoid the introduction of contamination during reconstitution and use. Use only sterile needles and syringes for administration.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Lyophilisate: Store and transport refrigerated (2 °C - 8 °C).
Solvent of 5 and 25 doses: Store and transport refrigerated (2 °C - 8 °C).
Solvent of 30 doses: Do not store and transport above 25 ºC.
Do not freeze.
Keep the bottles in the box in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the cardboard box and the label after Exp. The expiry date refers to the last day of that month.

Shelf-life after reconstitution according to directions: 6 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:

EU/2/10/114/001
EU/2/10/114/002
EU/2/10/114/003

Pack sizes:
Cardboard box containing 1 bottle with 5 doses of lyophilisate and 1 bottle with 10 ml of solvent.
Cardboard box containing 1 bottle with 25 doses lyophilisate and 1 bottle with 50 ml of solvent.
Cardboard box containing 1 bottle with 30 doses of lyophilisate.
Cardboard box containing 1 bottle with 60 ml of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona) SPAIN
TEL: +34 972 43 06 60

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

Local representatives and contact details to report suspected adverse reactions:

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