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:

Lyophilisate:
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

Solvent:
Phosphate buffer solution.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Suspension after reconstitution: transparent pinkish liquid.
Lyophilisate: white to yellowish powder.
Solvent: transparent homogenous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves and adult cows).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy animals only.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Common adverse reactions:

A slight increase in body temperature up to 1 °C is common within 4 days following vaccination. Commonly, 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.

A transient inflammation at the inoculation site is common in cattle within 72 hours post-vaccination. This slight swelling lasts for less than 24 hours in most cases.

Very rare adverse reactions:

Vaccination might very rarely cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment 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

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.

4.9 Amounts to be administered and administration route

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.

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.

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

No adverse reactions except those mentioned in section 4.6 were observed after the administration of a 10-fold vaccine dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines, bovine rhinotracheitis virus (IBR).
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatine
Povidone
Monosodium glutamate
Sodium chloride
Potassium chloride
Sucrose
Water for injections
Solvent:

Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 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.

6.4. 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.

6.5 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.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 430660

Fax. +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/01/2011
Date of last renewal: 06/11/2015

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of HIPRABOVIS IBR MARKER LIVE may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use of HIPRABOVIS IBR MARKER LIVE must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances
Laboratorios Hipra, S.A.
Avda la Selva, 135
17170 Amer (Girona)
SPAIN

Laboratorios Hipra, S.A.
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
17170 Amer (Girona)
SPAIN

Name and address of the manufacturer responsible for batch release
Laboratorios Hipra, S.A.
Avda la Selva, 135
17170 Amer (Girona)
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not in the scope of Regulation (EC) 470/2009.

The excipients listed in section 6.1 of the SPC are either allowed substances for which Table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

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. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

5 doses
25 doses

5. TARGET SPECIES

Cattle (calves and adult cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use by 6 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottles in the box in order to protect from light.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX: 30 DOSES LYOPHILISATE

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. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

4. PACKAGE SIZE

30 doses

5. TARGET SPECIES

Cattle (calves and adult cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use by 6 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottles in the box in order to protect from light.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/114/003

17. MANUFACTURER'S BATCH NUMBER

Batch {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. PHARMACEUTICAL FORM

4. PACKAGE SIZE

60 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {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 lyophilisate for suspension for injection for cattle.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

5 doses
25 doses
30 doses

4. ROUTE(S) OF ADMINISTRATION

I.M.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {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

BOTTLE FOR THE SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for HIPRABOVIS IBR MARKER LIVE

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

10 ml
50 ml
60 ml

3. ROUTE(S) OF ADMINISTRATION

I.M.
Read the package leaflet before use.

4. WITHDRAWAL PERIOD(S)

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/ year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HIPRABOVIS IBR MARKER LIVE
lyophilisate and solvent for 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 and manufacturer responsible for batch release:
LABORATORIOS HIPRA, S.A.
Avda la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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

Solvent:
Phosphate buffer solution.

Suspension after reconstitution: transparent pinkish liquid.
Lyophilisate: white to yellowish powder.
Solvent: transparent homogenous liquid.

4. INDICATION(S)

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. ADVERSE REACTIONS

Common adverse reactions:

A slight increase in body temperature up to 1 °C is common within 4 days following vaccination. Commonly, 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.

A transient inflammation at the inoculation site is common in cattle within 72 hours post-vaccination. This slight swelling lasts for less than 24 hours in most cases.

Very rare adverse reactions:

Vaccination might very rarely cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment 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).

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

7. TARGET SPECIES

Cattle (calves and adult cows).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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 PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Lyophilisate of 5, 25 and 30 doses: 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 after the expiry date (EXP) stated on the box and the label.

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

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate healthy animals only.

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 (symptoms, emergency procedures, antidotes):
No adverse reactions except those mentioned in section 6 “Adverse reactions” were observed after the administration of a 10-fold vaccine dose.

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

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

Österreich HIPRA DEUTSCHLAND GmbH Münsterstraße 306 40470 Düsseldorf DEUTSCHLAND e-mail: deutschland@hipra.com	**België/Belgique/Belgien** HIPRA BENELUX NV Adequat Business Center Brusselsesteenweg 159 9090 Melle e-mail: benelux@hipra.com
Deutschland HIPRA DEUTSCHLAND GmbH Münsterstraße 306 40470 Düsseldorf e-mail: deutschland@hipra.com	**Ελλάδα** HIPRA ΕΛΛΑΣ Α.Ε. Ψυχάρη 3 / 184 53 Νίκαια Τηλ: 210 4978660 - Fax: 210 4978661 e-mail: greece@hipra.com
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