

[Version 8, 10/2012]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE lyophilisate and suspension for suspension for injection for bovine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (3 ml) contains:

Active substances:

Lyophilised fraction:

Bovine respiratory syncytial virus, live attenuated, strain Lym-56 $\geq 10^4$ CCID₅₀*

* CCID₅₀: Cellular culture infective dose 50

Liquid fraction:

Parainfluenza-3 virus, inactivated, strain SF4 HAI* ≥ 16

Bovine viral diarrhoea virus, inactivated, strain NADL SN** ≥ 20

* HAI: mean haemagglutination inhibition titre induced in rabbits (≥ 480 HAU before inactivation).

** SN: mean serum neutralisation titre induced in rabbits ($\geq 10^6$ CCID₅₀ before inactivation).

Adjuvants:

Aluminium hydroxide (Al³⁺) 6.34 mg

Excipients:

Thimerosal (preservative) 0.3 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

The lyophilisate is a yellowish tablet.

The suspension is a pinkish liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Bovine (cows, heifers and calves).

4.2 Indications for use, specifying the target species

Cows and heifers: prevention of bovine viral diarrhoea (including the disease of the mucosae) (BVD).

Calves: prevention of the Parainfluenza 3 (PI3) virus, disease of the mucosae or bovine viral diarrhoea (BVD) and pneumonia by bovine respiratory syncytial virus (BRS).

Immunity starts three weeks after the first of administration and lasts 12 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Only healthy animals should be vaccinated.

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

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

An anaphylactic reaction may occur on very rare occasions in some sensitive animals. In that case, appropriate treatment such as with antihistaminics, epinephrine or similar 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)

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.

Bovine: administer one dose (3 ml) as of four weeks of age.

Resuspend the lyophilised fraction with the liquid fraction and shake before using.
Administer the vaccine when it is at ambient temperature, between +15 and +25°C.

The administration method is by intramuscular injection in the neck muscles, or subcutaneously in the dewlap.

Recommended vaccinal schedule:

Calves:

Primary vaccination: administer one dose. It is advisable to administer a second dose 21-30 days later, especially if very young animals are vaccinated.

Revaccination: one vaccination every 12 months.

Cows:

Primary vaccination: administer one dose, followed by a second dose 21-30 days later.

Revaccination: one vaccination every 12 months.

Heifers:

Primary vaccination: administer one dose, followed by a second dose 21-30 days later, a month before the first mating.

Revaccination: one vaccination every 12 months.

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 and inactivated viral vaccines for the bovine species.

ATCvet code: QI02AH

Induces active immunity against the BVD, PI-3 and BRSV viruses to prevent bovine respiratory syndrome and reproductive failure associated with BVD.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid fraction:

Aluminium hydroxide gel

Simethicone

Thimerosal

Water for injections

Lyophilised fraction:

Disodium phosphate dodecahydrate

Potassium dihydrogen phosphate

Gelatine

Povidone 30

Sodium chloride

Sucrose

Monosodium glutamate

Potassium chloride

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf life after dilution or reconstitution according to directions: 3 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Liquid fraction: contained in a Type I, 20-ml, amber coloured glass vial containing 15 ml (5 doses) (in accordance with the current edition of the Ph.Eur.), 100-ml amber coloured glass flasks containing 90 ml (30 doses), and Type II 250-ml (80 doses) (in accordance with the current edition of the Ph.Eur.) containing 240 ml, with their corresponding bromobutyl elastomer closures classified as Type I (in accordance with the current edition of the Ph.Eur.), and anodized aluminium caps.

Lyophilised fraction: contained in 10-ml (5, 30 and 80 doses), colourless, Type I glass vials (in accordance with current edition of the Ph.Eur.), bromobutyl elastomer closures classified as Type I (in accordance with the current edition of the Ph.Eur.), and anodized aluminium caps.

Package sizes:

- Box with 1 vial of lyophilised fraction (5 doses) + 1 vial of 20 ml of liquid fraction (containing 15 ml)
- Box with 1 vial lyophilised fraction (30 doses) + 1 vial of 100 ml of liquid fraction (containing 90 ml)
- Box with 1 vial lyophilised fraction (80 doses) + 1 vial of 250 ml of liquid fraction (containing 240 ml)

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/07/2008

Date of last renewal: {DD/MM/YYYY}

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{ LABEL OF THE LIQUID FRACTION OF 5 DOSES – 20-ml glass vial }
5 doses (15 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE liquid fraction

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (3 ml) contains:

Parainfluenza-3 virus, inactivated, strain SF4: HAI \geq 16; Bovine viral diarrhoea virus, inactivated, strain NADL: SN \geq 20; Adjuvant -Aluminium hydroxide (Al³⁺): 6.34 mg;

Thimerosal (preservative): 0.3 mg

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

5 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use or subcutaneous use.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Once reconstituted, use within 3 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**LABEL OF THE LIQUID FRACTION FOR 30 DOSES (100-ml flask) / 80 DOSES (250-ml flask)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HIPRABOVIS BALANCE liquid fraction

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (3 ml) contains:

Active substances:Liquid fraction:

Parainfluenza-3 virus, inactivated, strain SF4 HAI* ≥ 16

Bovine viral diarrhoea virus, inactivated, strain NADL SN** ≥ 20

* HAI: mean haemagglutination inhibition titre induced in rabbits (≥ 480 HAU before inactivation).

** SN: mean serum neutralisation titre induced in rabbits ($\geq 10^6$ TCID₅₀ before inactivation).

Adjuvants:

Aluminium hydroxide (Al³⁺) 6.34 mg

Excipients

Thimerosal (preservative) 0.3 mg

3. PHARMACEUTICAL FORM

Liquid fraction.

4. PACKAGE SIZE

30 doses (90 ml)

80 doses (240 ml)

5. TARGET SPECIES

Bovine (cows, heifers and calves).

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Dose: 3 ml / animal.

Resuspend the lyophilised fraction with the liquid fraction and shake before use.

Administer the vaccine when at ambient temperature, between +15 and +25°C.

Route of administration: intramuscular, in the neck muscles, or subcutaneously in the dewlap.

Read the package leaflet before use.

8. 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}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Protect from light. Do not freeze.
Once reconstituted, use within 3 hours.

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)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABEL OF THE LYOPHILISED FRACTION}

5 doses/ 30 doses/ 80 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE lyophilised fraction

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (3 ml) contains:

Bovine respiratory syncytial virus, live attenuated, strain Lym-56 live $\geq 10^4$ CCID₅₀** CCID₅₀: Cellular culture infective dose 50**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

5 doses

30 doses

80 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use or subcutaneous use.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

Once reconstituted, use within 3 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**{CARDBOARD BOX}****5 doses/ 30 doses/ 80 doses (1 vial lyophilised fraction + 1 vial liquid fraction)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

HIPRABOVIS BALANCE lyophilisate and suspension for suspension for injection for bovine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCESEach dose (3 ml) contains:**Active substances:****Lyophilised fraction:**Bovine respiratory syncytial virus, live attenuated, strain Lym-56 $\geq 10^4$ CCID₅₀** CCID₅₀: Cellular culture infective dose 50**Liquid fraction:**Parainfluenza-3 virus, inactivated, strain SF4 HAI* ≥ 16 Bovine viral diarrhoea virus, inactivated, strain NADL SN** ≥ 20 * HAI: mean haemagglutination inhibition infective titre induced in rabbits (≥ 480 HAU before inactivation).** SN: mean serum neutralisation titre induced in rabbits ($\geq 10^6$ CCID₅₀ before inactivation).**Adjuvants:**Aluminium hydroxide (Al³⁺) 6.34 mg**Excipients**

Thimerosal (preservative) 0.3 mg

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

1 vial of lyophilised fraction (10 ml) and 1 vial of 20 ml of liquid fraction (5 doses)

1 vial of lyophilised fraction (10 ml) and 1 vial of 100 ml of liquid fraction (30 doses)

1 vial of lyophilised fraction (10 ml) and 1 vial of 250 ml of liquid fraction (80 doses)

5. TARGET SPECIES

Bovine (cows, heifers and calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 3 ml / animal.

Resuspend the lyophilised fraction with the liquid fraction and shake before use.

Administer the vaccine when at ambient temperature, between +15 and +25°C.

Route of administration: intramuscular, in the neck muscles, or subcutaneously in the dewlap.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY
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Read the package leaflet before use.

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Once reconstituted, use within 3 hours.

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)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

HIPRABOVIS BALANCE lyophilisate and suspension for suspension for injection for bovine

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

Tel. (34) 972 43 06 60

Fax (34) 972 43 06 61

E-mail: hipra@hipra.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE lyophilisate and suspension for suspension for injection for bovine

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

Each dose (3 ml) contains:

Active substances:

Lyophilised fraction:

Bovine respiratory syncytial virus, live attenuated, strain Lym-56 $\geq 10^4$ CCID₅₀*

* CCID₅₀: Cellular culture infective dose 50

Liquid fraction:

Parainfluenza-3 virus, inactivated, strain SF4 HAI* ≥ 16

Bovine viral diarrhoea virus, inactivated, strain NADL SN** ≥ 20

* HAI: mean haemagglutination inhibition titre induced in rabbits (≥ 480 HAU before inactivation).

** SN: mean serum neutralisation titre induced in rabbits ($\geq 10^6$ TCID₅₀ before inactivation).

Adjuvants:

Aluminium hydroxide (Al³⁺) 6.34 mg

Excipients

Thimerosal (preservative) 0.3 mg

Lyophilisate and suspension for suspension for injection.

The lyophilisate is a yellowish tablet.

The suspension is a pinkish liquid.

4. INDICATION(S)

Cows and heifers: prevention of bovine viral diarrhoea (including the disease of the mucosas) (BVD).

Calves: prevention of the Parainfluenza 3 (PI3) virus, disease of the mucosas or bovine viral diarrhoea (BVD) and pneumonia by bovine respiratory syncytial virus (BRS).

Immunity starts three weeks after the first of administration and lasts 12 months.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

An anaphylactic reaction may occur on very rare occasions in some sensitive animals. In that case, appropriate treatment such as with antihistaminics, epinephrine or similar 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

Bovine (cows, heifers and calves).

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

Bovine: administer one dose (3 ml), as of four weeks of age.

The administration method is by intramuscular injection in the neck muscles, or subcutaneously in the dewlap.

Recommended vaccinal schedule:

Calves:

Primary vaccination: administer one dose. It is advisable to administer a second dose 21-30 days later, especially if very young animals are vaccinated.

Revaccination: one vaccination every 12 months.

Cows:

Primary vaccination: administer one dose, followed by a second dose 21-30 days later.

Revaccination: one vaccination every 12 months.

Heifers:

Primary vaccination: administer one dose, followed by a second dose 21-30 days later, a month before the first mating.

Revaccination: one vaccination every 12 months.

9. ADVICE ON CORRECT ADMINISTRATION

Resuspend the lyophilised fraction with the liquid fraction and shake before use.

Administer the vaccine when it is at ambient temperature, between +15 and +25°C.

Once reconstituted, use within 3 hours.

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). Protect from light. Do not freeze.

Store the container in the outer packaging to protect it from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/box after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Only healthy animals should be vaccinated.

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

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay:

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 “Adverse reactions” were observed after the administration of a 10-fold vaccine dose.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

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

Ask your veterinary surgeon or pharmacist 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

15. OTHER INFORMATION

Pack sizes:

-Box with 1 vial of lyophilised fraction (5 doses) + 1 vial of 20 ml of liquid fraction (containing 15 ml)

-Box with 1 vial lyophilised fraction (30 doses) + 1 vial of 100 ml of liquid fraction (containing 90 ml)

-Box with 1 vial lyophilised fraction (80 doses) + 1 vial of 250 ml of liquid fraction (containing 240 ml)

Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.