*[Version 8.2,01/2021]*

**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:
***Lyophilisate fraction:***
Bovine respiratory syncytial virus, attenuated, strain Lym-56 …….....≥ $10^4$ $CCID_{50}$*
* $CCID_{50}$: Cell 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. (≥ $10^6$ $CCID_{50}$ before inactivation)

**Adjuvant:**
Aluminium hydroxide ($Al^{3+}$)..... 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 Mucosa Disease) (BVD).

Calves: Prevention of Parainfluenza 3 (PI3), Mucosa Disease or Bovine Viral Diarrhoea (BVD) and of Pneumonia caused by Bovine Respiratory Syncytial virus (BRS).

Immunity starts 3 weeks after the first 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

Vaccinate only healthy animals.

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 very rarely in a sensitized animal. In this case, appropriate treatment, using antihistamines, epinephrine, or a similar drug, is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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 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 4 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 +25ºC.

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

Recommended vaccinal schedule:

Calves:
Primary vaccination: administer one dose. It is advisable to administer a second dose at 21-30 days, especially if very young animals are vaccinated.
Revaccination: one vaccination every 12 months.

Cows:
Primary vaccination: administer one dose, followed by a second dose at 21-30 days.
Revaccination: one vaccination every 12 months.

Heifers:
Primary vaccination: administer one dose, followed by a second dose at 21-30 days, a month before the first mating.
Revaccination: one vaccination every 12 months.

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

Adverse reactions other than those already mentioned under section 4.6, observed after the administration of 10 doses of vaccine, are not expected.

### 4.11 Withdrawal period(s)

Zero days

## 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live and inactivated viral vaccines for the bovine species.
ATCvet code: QI02AH.
To stimulate active immunity against the BVD, PI-3 and BRS viruses in order to prevent bovine respiratory syndrome and reproductive failure associated with the BVD virus.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Liquid fraction:*
Aluminium hydroxide
Dimethicone
Thimerosal
Water for injections

*Lyofilisated fraction:*
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatine
Povidone
Sodium chloride
Sucrose
Monosodium glutamate
Sodium chloride

### 6.2 Major 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 (between 2 ºC and 8 ºC).
Protect from light.
Do not freeze.

## 6.5 Nature and composition of immediate packaging

Liquid fraction: the container is composed of Type I, 20-ml, amber coloured glass vials with 15 ml (5 doses) (in accordance with the current edition of the Ph.Eur), 100-ml amber coloured glass flasks with 90 ml (25 and 30 doses) and Type II 250 ml with 240 ml (80 doses) (in accordance with the current edition of the Ph.Eur), 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: the container is composed of Type I, colourless, 10-ml (5, 25, 30 and 80 doses), 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.

Pack sizes:
-Box with 1 vial of lyophilised fraction (5 doses) + one 20-ml vial of liquid fraction (with 15 ml).
-Box with 1 vial lyophilised fraction (25 doses) + one 100-ml vial of liquid fraction (with 75 ml)
-Box with 1 vial lyophilised fraction (30 doses) + one 100-ml vial of liquid fraction (with 90 ml).
-Box with 1 vial lyophilised fraction (80 doses) + one 250-ml vial of liquid fraction (with 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)

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## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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## 10 DATE OF REVISION OF THE TEXT

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**PROHIBITION OF SALE, SUPPLY AND/OR USE**

For animal treatment only. Medicine subject to a veterinary prescription.
Administration under control or supervision of the veterinarian.