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B. PACKAGE LEAFLET

PACKAGE LEAFLET:
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:
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

Excipient:
Thimerosal (preservative)..... 0.3 mg

Lyophilisate and solvent for preparation 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 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 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 eight weeks of age.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
Once reconstituted, use within a 3-hour period.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC and 8 ºC). Do not freeze.
Store the container in the outer packaging to protect it from light.
Do not use after the date of expiry that appears on the label/box after EXP.

12. SPECIAL WARNING(S)

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.

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 needs to be made on a case-by-case basis.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
Adverse reactions other than those already mentioned under "Adverse reactions", observed after the administration of 10 doses of vaccine, are not expected.

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

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15. OTHER INFORMATION

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.

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