[Version 8.2,01/2021]

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)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE liquid fraction

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (3ml) contains:
Parainfluenza-3 virus, inactivated, strain SF4: HAI ≥ 16, Bovine viral diarrhoea virus, inactivated, strain NADL: SN ≥ 20, Adjuvant – Aluminium hydroxide (Al^{3+}): 6.34 mg; Thimerosal (Preservative): 0.3 mg

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

5 doses (15 ml).

4. ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}
Once reconstituted, use within a 3-hour period.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LIQUID FOR 25 DOSES (75-ml BOTTLE) / 30 DOSES (100-ml BOTTLE) / 80 DOSES (250-ml BOTTLE)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS BALANCE liquid fraction.

2. STATEMENT OF ACTIVE 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 infective 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

3. PHARMACEUTICAL FORM

Liquid fraction.

4. PACKAGE SIZE

25 doses (75 ml)
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 +25ºC.

Route of administration: intramuscular, in the neck muscles, or subcutaneous in the dewlap.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 ºC and 8 ºC). Protect from light. Do not freeze.
Once reconstituted, use within a 3-hour period.

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. The vaccine 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/ 25 doses / 30 doses/ 80 doses

2. 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, strain Lym-56 attenuated …..... $\geq 10^4$ $CCID_{50}$*
*$CCID_{50}$: cell culture infective dose 50%

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

5 doses
25 doses
30 doses
80 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Batch {number}.

7. EXPIRY DATE

EXP: {month/year}
Once reconstituted, use within a 3-hour period.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARBOARD BOX
5 doses/ 25 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 preparation of suspension for injection for bovine

2. STATEMENT OF ACTIVE SUBSTANCES

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)

Adjuvants:
Aluminium hydroxide (Al^{3+})..... 6.34 mg

Excipient:
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 75 ml of liquid fraction (25 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 +25ºC.

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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental self-injection is dangerous.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (between 2 ºC and 8 ºC). Protect from light. Do not freeze.
Once reconstituted, use within a 3-hour period.

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. The vaccine is 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}