ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIVENCE PENTA lyophilisate and solvent for emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:

Live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56	$10^{5.2}$ - $10^{6.5}$ $CCID_{50}$*
Live gE- tk- double-gene deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL	$10^{6.3}$ - $10^{7.6}$ $CCID_{50}$*
Inactivated bovine parainfluenza 3 virus (PI-3), strain SF4	≥ 206.2 EU**
E2 recombinant protein from bovine viral diarrhoea virus type 1 (BVDV-1)	≥ 31.6 EU**
E2 recombinant protein from bovine viral diarrhoea virus type 2 (BVDV-2)	≥ 21.0 EU**

gE-: deleted glycoprotein E; tk-: deleted thymidine kinase
E2: E2 structural glycoprotein
* Cell Culture Infectious Dose 50 %
** ELISA Units

Adjuvant:

Montanide IMS	1.010 g

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Dipotassium phosphate
Gelatin
Glycine
Potassium dihydrogen phosphate
Sorbitol
Sucrose
Solvent:
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Lyophilisate: white-to-yellow colour.
Solvent: white translucent emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

Active immunisation of cattle from 10 weeks of age:

BRSV and PI-3: to reduce virus shedding, hyperthermia, clinical signs and lung lesions.

BoHV-1: to reduce virus shedding, hyperthermia and clinical signs of IBR (infectious bovine rhinotracheitis).

BVDV: to reduce viremia, hyperthermia and leukopenia caused by BVDV-1 and BVDV-2 and virus shedding caused by BVDV-2.

Active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of BVDV (type 1 and 2).

Onset of immunity:

3 weeks after completion of the basic vaccination scheme.

Protection of transplacental infection from BVDV (type 1 and 2) is achieved 3 weeks after completion of the re-vaccination scheme.

Duration of immunity:

6 months after completion of the basic vaccination scheme.
1 year after completion of the re-vaccination scheme.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected,

accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site inflammation[1], elevated temperature[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reaction[3]. Milk production decrease [4] . Reduced food intake[4], Decreased activity[4] .

[1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.

[2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsides spontaneously within 3 days.

[3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.

[4] Observed in dairy cows, mostly after application of primary dose.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

For use in cattle from 10 weeks of age onwards.

Basic vaccination scheme: administer two doses (2 ml each) with an interval of 3 weeks.

Re-vaccination scheme: one dose of 2 ml should be administered at an interval not longer than 6 months after completion of the basic vaccination scheme.

Subsequent re-vaccination scheme: one dose of 2 ml should be administered at an interval not longer than 12 months.

Method of administration:
Avoid contamination during reconstitution and use. Use only sterile needles and syringes for administration.

Reconstitute the lyophilisate with the entire content of the supplied solvent to obtain an emulsion for injection.

The reconstituted vaccine is a white-to-yellow emulsion.

Allow the vaccine to reach a temperature of +15 to + 25 °C before administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those described in section 3.6 were observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release may be required for this product according to national requirements.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AH

To stimulate active immunity against bovine respiratory syncytial virus (BRSV), bovine herpesvirus type 1 (BoHV-1), bovine parainfluenza 3 virus (PI-3) and bovine viral diarrhoea virus types 1 and 2 (BVDV-1 and BVDV-2).

The duration of immunity of one year after re-vaccination for BRSV and PI-3 is based on results of serological studies.

For bovine herpesvirus type 1, vaccinated animals can be differentiated from field virus infected animals, due to the marker deletion (gE-), by means of commercial diagnostic kits.

For BVDV, the vaccine only contains the immunogenic glycoprotein E2, present in BVDV-1 and BVDV-2. Hence, since vaccination does not induce the production of antibodies against any other protein present in BVDV-1 and BVDV-2 different from E2 (marker vaccine), vaccinated animals can be differentiated from field virus infected animals by means of commercial diagnostic kits.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life of the solvent as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Lyophilisate: 10 or 50 ml type I glass vials containing 5 doses, 10 doses or 20 doses closed with bromobutyl rubber stoppers and sealed with aluminium caps.

Solvent: Polyethylene (PET) vials of 10 ml, 20 ml or 50 ml closed with bromobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:
Cardboard box containing 1 vial of 5 doses of lyophilisate and 1 vial of 10 ml of solvent.
Cardboard box containing 1 vial of 10 doses of lyophilisate and 1 vial of 20 ml of solvent.
Cardboard box containing 1 vial of 20 doses of lyophilisate and 1 vial of 40 ml of solvent.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/307/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/04/2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIVENCE PENTA lyophilisate and solvent for emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

Live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56	$10^{5.2}$ - $10^{6.5}$ $CCID_{50}$
Live gE- tk- double-gene deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL	$10^{6.3}$ - $10^{7.6}$ $CCID_{50}$
Inactivated bovine parainfluenza 3 virus (PI-3), strain SF4	≥ 206.2 EU
E2 recombinant protein from bovine viral diarrhoea virus type 1 (BVDV-1)	≥ 31.6 EU
E2 recombinant protein from bovine viral diarrhoea virus type 2 (BVDV-2)	≥ 21.0 EU

3. PACKAGE SIZE

One vial of 5 doses of lyophilisate and one vial of 10 ml of solvent.
One vial of 10 doses of lyophilisate and one vial of 20 ml of solvent.
One vial of 20 doses of lyophilisate and one vial of 40 ml of solvent.

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/307/001 (5 doses)
EU/2/24/307/002 (10 doses)
EU/2/24/307/003 (20 doses)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of lyophilisate (5 doses, 10 doses or 20 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIVENCE PENTA lyophilisate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 2 ml contains:

Live attenuated BRSV, strain Lym-56	$10^{5.2}$ - $10^{6.5}$ $CCID_{50}$
Live gE- tk- double-gene deleted BoHV type 1, strain CEDDEL	$10^{6.3}$ - $10^{7.6}$ $CCID_{50}$
Inactivated PI-3 virus, strain SF4	≥ 206.2 EU
E2 recombinant protein from BVDV-1	≥ 31.6 EU
E2 recombinant protein from BVDV-2	≥ 21.0 EU

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

5 doses
10 doses
20 doses

4. BATCH NUMBER

Lot {number}

5. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

Vial of solvent (10 ml, 20 ml or 40 ml)

1. NAME OF THE SOLVENT

Solvent for DIVENCE PENTA

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

10 ml
20 ml
40 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DIVENCE PENTA lyophilisate and solvent for emulsion for injection

2. Composition

Each dose of 2 ml contains:

Active substances:

Live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56	$10^{5.2}$ - $10^{6.5}$ $CCID_{50}$*
Live gE- tk- double-gene deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL	$10^{6.3}$ - $10^{7.6}$ $CCID_{50}$*
Inactivated bovine parainfluenza 3 virus (PI-3), strain SF4	≥ 206.2 EU**
E2 recombinant protein from bovine viral diarrhoea virus type 1 (BVDV-1)	≥ 31.6 EU**
E2 recombinant protein from bovine viral diarrhoea virus type 2 (BVDV-2)	≥ 21.0 EU**

gE-: deleted glycoprotein E; tk-: deleted thymidine kinase
E2: E2 structural glycoprotein
* Cell Culture Infectious Dose 50 %
** ELISA Units

Adjuvant:

Montanide IMS	1.010 g

Lyophilisate: white-to-yellow colour.
Solvent: white translucent emulsion.

3. Target species

Cattle.

4. Indications for use

Active immunisation of cattle from 10 weeks of age:

BRSV and PI-3: to reduce virus shedding, hyperthermia, clinical signs and lung lesions.

BoHV-1: to reduce virus shedding, hyperthermia and clinical signs of IBR (infectious bovine rhinotracheitis).

BVDV: to reduce viremia, hyperthermia and leukopenia caused by BVDV-1 and BVDV-2 and virus shedding caused by BVDV-2.

Active immunisation of heifers and cows to reduce births of persistently infected calves and transplacental infection of BVDV (type 1 and 2).

Onset of immunity:
3 weeks after completion of the basic vaccination scheme.

Protection of transplacental infection from BVDV (type 1 and 2) is achieved 3 weeks after completion of the re-vaccination scheme.

Duration of immunity:
6 months after completion of the basic vaccination scheme.
1 year after completion of the re-vaccination scheme.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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:
No adverse reactions other than those described in the “adverse events” section were observed.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Official control authority batch release may be required for this product according to national requirements.

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

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):
Injection site inflammation[1], elevated temperature[2].
Uncommon (1 to 10 animals / 1,000 animals treated):
Anaphylactic-type reaction[3]. Milk production decrease [4] . Reduced food intake[4], Decreased activity[4] .

[1] A slight to moderate transient injection site inflammation (up to 14 cm of diameter) may be observed, which rapidly decreases in diameter within 2 days and subsides within 2 weeks without treatment.

[2] An elevated temperature (mean increase 1.7 ºC, in individual animals up to 2.4 ºC) may occur after vaccination. This increase subsided spontaneously within 3 days.

[3] In cases of anaphylactic-type reactions, an appropriate symptomatic treatment should be administered.

[4] Observed in dairy cows, mostly after application of primary dose.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.
For use in cattle from 10 weeks of age onwards.

Basic vaccination scheme: administer two doses (2 ml each) with an interval of 3 weeks.

Re-vaccination scheme: one dose of 2 ml should be administered at an interval not longer than 6 months after completion of the basic vaccination scheme.

Subsequent re-vaccination scheme: one dose of 2 ml should be administered at an interval not longer than 12 months.

9. Advice on correct administration

Avoid contamination during reconstitution and use. Use only sterile needles and syringes for administration.

Reconstitute the lyophilisate with the entire content of the supplied solvent to obtain an emulsion for injection.

The reconstituted vaccine is a white-to-yellow emulsion.

Allow the vaccine to reach a temperature of +15 to + 25 °C before administration.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/24/307/001-003

Pack sizes:
Cardboard box containing 1 vial of 5 doses of lyophilisate and 1 vial of 10 ml of solvent.
Cardboard box containing 1 vial of 10 doses of lyophilisate and 1 vial of 20 ml of solvent.
Cardboard box containing 1 vial of 20 doses of lyophilisate and 1 vial of 40 ml of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Local representatives and contact details to report suspected adverse reactions:

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

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17. Other information

For bovine herpesvirus type 1 (BoHV-1), vaccinated animals can be differentiated from field virus infected animals, due to the marker deletion (gE-), by means of commercial diagnostic kits.

For BVDV, the vaccine only contains the immunogenic glycoprotein E2, present in BVDV-1 and BVDV-2. Thus, vaccinated animals can be differentiated from field virus infected animals by means of commercial diagnostic kits.