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)
≥ 34.5 EU

E2 recombinant protein from bovine viral diarrhoea virus type 2 (BVDV-2)
≥ 23.7 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 SA

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/5019

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	≥ 34.5 EU
E2 recombinant protein from BVDV-2	≥ 23.7 EU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

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

5 doses
10 doses
20 doses

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING OF THE SOLVENT
(Vials of solvent (10 ml, 20 ml or 40 ml)

1. NAME OF THE DILUENT/SOLVENT

Solvent for DIVENCE PENTA

2. TARGET SPECIES

Cattle.

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

10 ml
20 ml
40 ml

4. ROUTE OF ADMINISTRATION

Intramuscular use.

5. EXPIRY DATE

Exp. {month/year}

6. SPECIAL STORAGE PRECAUTIONS

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

7. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA

8. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE 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)
≥ 34.5 EU**

E2 recombinant protein from bovine viral diarrhoea virus type 2 (BVDV-2)
≥ 23.7 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 from 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.
Reduction 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 for BoHV-1 and BVDV (type 1 and type 2) .

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.
Special precautions for use 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 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 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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interactions 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 mentioned in “adverse events” section were observed.

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].

[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.

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 of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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.

DIVENCE IBR MARKER LIVE may be used for subsequent re-vaccinations after vaccination with DIVENCE PENTA if there is no further need for protection against BRSV, PI-3 and BVDV.

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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC - 8 ºC). 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

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.

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15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

17. Other information

POM-V

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.

For animal treatment only.

Gavin Hall

Approved: 10 January 2025