

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIVENCE TRI 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 <sub>50</sub> *
Live gE- tk- double-gene deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL	$10^{6.3} - 10^{7.6}$ CCID <sub>50</sub> *
Inactivated bovine parainfluenza-3 virus (PI-3), strain SF4	$\geq 206.2$ EU**

gE-: deleted glycoprotein E; tk-: deleted thymidine kinase

\* Cell Culture Infectious Dose 50 %

\*\* ELISA Units

### Adjuvant:

Montanide IMS 1.010 g

### Excipients:

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

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).

Onset of immunity: 3 weeks after completion of the basic 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 <sup>1</sup> , elevated temperature <sup>2</sup>
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reaction <sup>3</sup>

<sup>1</sup> 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.

<sup>2</sup> An elevated temperature (mean increase 1.7 °C, in individual animals up to 2.4 °C) may occur after vaccination. This increase subsides spontaneously within 3 days.

<sup>3</sup> 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder 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.

DIVENCE TRI may be used for subsequent re-vaccinations after vaccination with DIVENCE PENTA if there is no further need for protection against BVDV.

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

#### 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.

### **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**

Not applicable.

### **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) and bovine parainfluenza 3 virus (PI-3).

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.

## **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: 21 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)**

VPA 10846/020/001

**8. DATE OF FIRST AUTHORISATION**

**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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).