SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIVENCE IBR MARKER LIVE lyophilisate and solvent for emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Live gE- tk- double-gene deleted bovine herpesvirus type 1 (BoHV-1), strain CEDDEL $10^{6.3}$ - $10^{7.6}$ $CCID_{50}$*

gE-: deleted glycoprotein E; tk-: deleted thymidine kinase
* Cell culture infectious dose 50%

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 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[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] A temporary mild reduction in milk production, feed intake and activity may uncommonly be observed in dairy cows mostly after the first 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 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 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.
The vaccine may be used for subsequent re-vaccinations after vaccination with DIVENCE TRI vaccine if there is no further need for protection against BRSV and PI-3, where available.

Method of administration:
Avoid contamination during reconstitution and use. Use only sterile needles and syringes for administration.
Reconstitute the lyophilisate with the corresponding volume of solvent:

Number of doses per vial of lyophilisate	Volume of solvent to be used
5 doses	10 ml
20 doses	40 ml
40 doses	80 ml
50 doses	100 ml

Peel the top off the aluminium cap on the vial containing the solvent and withdraw 10 ml of volume.
Inject the solvent into the vial containing the lyophilisate.
Shake until the lyophilisate is in emulsion. The 5-doses vial is now ready to use.
For the 20, 40 and 50 doses vials, once the lyophilisate is in emulsion with the 10 ml of solvent, withdraw all the emulsion obtained from the vaccine vial and inject it into the vial containing the remaining solvent.
Shake until the lyophilisate is in emulsion.

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

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

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

No adverse reactions other than those mentioned 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.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AD01 - bovine rhinotracheitis virus (IBR).

Vaccinated animals can be differentiated from field virus infected animals due to the marker deletion (gE-) by means of commercial diagnostic kits.
To stimulate active immunity against bovine herpesvirus type 1 (BoHV-1).

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 ºC - 8 ºC).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate: 10 ml type I glass vials containing 5 doses, 20 doses, 40 doses or 50 doses closed with bromobutyl rubber stoppers and sealed with aluminium caps.
Solvent: Polyethylene (PET) vials of 10 ml, 50 ml or 100 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 20 doses of lyophilisate and 1 vial of 40 ml of solvent.
Cardboard box containing 1 vial of 40 doses of lyophilisate and 1 vial of 80 ml of solvent.
Cardboard box containing 1 vial of 50 doses of lyophilisate and 1 vial of 100 ml of solvent.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 SA

7. MARKETING AUTHORISATION NUMBER

Vm 17533/5018

8. DATE OF FIRST AUTHORISATION

14 October 2024

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 12 August 2025

Gavin Hall