1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhinovac IBR Marker live lyophilisate and solvent for suspension for injection or nasal spray for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose of reconstituted vaccine contains:
Active substances:
Bovine herpesvirus 1, strain BIO-27, gE-, Live: $10^{5.7} – 10^{7.5}$ $TCID_{50}$*

*$TCID_{50}$ – medium tissue culture infectious dose (50%)

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate medium:
Trometamol
Edetic acid (Chelaton II)
Sucrose
Dextran 70
Water for injections
Solvent:
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

The lyophilisate has a spongy consistency, a cream to yellowish colour.
The solvent is a clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the active immunisation of cattle to reduce the severity and duration of clinical signs and viral excretion caused by BHV-1 (infectious bovine rhinotracheitis; IBR) infections.

Onset of Immunity:
One week after nasal vaccination of calves from 2 weeks of age without maternally derived antibodies.
Two weeks after intramuscular vaccination of calves from 3 months of age.

Duration of immunity:

Ten weeks after nasal vaccination of calves from 2 weeks of age without maternally derived antibodies
Six months after intramuscular vaccination of calves from 3 months of age.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Maternal antibodies have been shown to have a negative impact on the efficacy of nasal vaccination of calves from 2 weeks of age, therefore the efficacy of nasal vaccination has been demonstrated only in seronegative calves. The presence of maternally derived antibodies in calves from 3 months of age do not interfere with the response to intramuscular vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Following nasal vaccination, vaccinated animals may shed the vaccine strain by the nasal route for up to 5 days. While this did not result in spread of the vaccine strain to unvaccinated animals that were in contact with vaccinated animals, the risk of spread cannot be fully excluded and therefore appropriate precautions should be taken to avoid spread if considered necessary.

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

In case of accidental self-injection or accidental exposure to aerosols, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]

[1] increase of 0.4 °C following intramuscular administration and increase of 1.0 °C following nasal administration, which resolves within 4 days.

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.

Fertility:

No information is available on the use of this vaccine in breeding bulls.

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 needs to be made on a case by case basis.

3.9 Administration routes and dosage

Intramuscular or nasal use.
Reconstitute the vaccine immediately before use by aseptically mixing lyophilisate with the solvent in 2 steps:
1. Inject a suitable volume of solvent on the lyophilised plug in the lyophilisate vial.
2. Shake well and extract the resuspended lyophilisate from the lyophilisate vial and mix with the rest of the solvent in the solvent vial.

Shake well before use.
After reconstitution, the slightly opalescent liquid has a pink-and-red or yellowish colour.

Primary Vaccination:
In the case of nasal administration aspirate the required volume of reconstituted vaccine, (1 ml of the vaccine for each nostril), with a syringe needle from the vial, then replace the needle with an applicator and administer the vaccine. The applicator is used to apply the desired amount of the vaccine in aerosol form from the syringe into the nostrils of a calf. The applicator used should spray the vaccine in the form of 30 µm to 100 µm droplets.

Dosage:
2 ml of reconstituted vaccine per animal.

Vaccination schedule:
There are two primary vaccination schedules depending on the age of the animal:
1. Calves from 2 weeks of age without maternal antibodies up to 3 months of age:
One nasal administration of one dose (2 ml) from 2 weeks of age.

Revaccination:
There is no information available on revaccination following nasal administration. Subsequent vaccination should be by administration of the primary vaccination schedule by the intramuscular route, taking into account that no longer than 10 weeks should elapse between nasal administration and the first intramuscular dose.

2. Cattle from 3 months of age:
One intramuscular administration of one dose (2 ml) per animal from 3 months of age.

Revaccination:
Revaccination is always intramuscular with one dose every 6 months after completion of the primary vaccination.

Sterile equipment free of disinfectants should be used for vaccination as disinfectants could reduce the efficacy of vaccination.

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

Administration of a 10-fold overdose of the vaccine did not cause any adverse effects.

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 :

QI02AD01

To stimulate active immunity against bovine herpes virus type 1 (BHV-1), infectious bovine rhinotracheitis (IBR).

Vaccination stimulates the production of antibodies in vaccinated cattle, which are detected in the serum neutralisation test and in conventional ELISA tests. With specific test kits these antibodies can be differentiated – due to the lack of antibodies against gE – from those of field virus infected animals to animals vaccinated with conventional vaccines.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product (lyophilisate) as packaged for sale: 2 years
Shelf life of the veterinary medicinal product (solvent) as packaged for sale: 4 years
Shelf life after reconstitution according to directions: 8 hours

5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C)
Protect from light
Store the reconstituted vaccine below 25 °C (for up to 8 hours).
Do not freeze.

5.4 Nature and composition of immediate packaging

Colourless hydrolytic type I glass vials, 3 ml, containing 5 doses of the lyophilised vaccine with a bromobutyl rubber stopper and an aluminium cap. The accompanying solvent is provided in colourless hydrolytic type I glass vials containing 10 ml of sterile buffered saline closed with a chlorobutyl stopper and an aluminium cap.

Colourless hydrolytic type I glass vials, 10 ml, containing 25 doses of the lyophilised vaccine with a bromobutyl rubber stopper and an aluminium cap. The accompanying solvent is provided in colourless hydrolytic type II glass vials containing 50 ml of sterile buffered saline closed with a chlorobutyl stopper and an aluminium cap.

Package sizes:

a) Plastic box with a lid with 10 wells containing 5 vials of lyophilised vaccine and 5 vials of 10 ml solvent – 25 doses of vaccine. Outers of 5 x 5 doses.
b) Cardboard box with 10 ml lyophilised vaccine and 50 ml solvent – 25 doses of vaccine.

Applicators are distributed together with the vaccine and packed separately.

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

Animal Health Distributors Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22715/004/001

8. DATE OF FIRST AUTHORISATION

10/09/2021

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

28/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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