SUMMARY OF PRODUCT CHARACTERISTICS

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 dose of 2ml reconstituted vaccine contains:

Active Substance:

Live attenuated bovine herpesvirus Type I (BHV-I), strain Bio-27: IBR (gE negative), $10^{5.7}$ – $10^{7.5}$ $TCID_{50}$*

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

Excipients:
For the full list of excipients see Pharmaceutical Particulars

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection or nasal spray.
The lyophilisate has a spongy consistency, a cream to yellowish colour.
The solvent is a clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the 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 intranasal 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 intranasal vaccination of calves from 2 weeks of age without maternally derived antibodies

Six months after intramuscular vaccination of calves from 3 months of age.

4.3 Contraindications

None

4.4 Special warnings for each target species

Maternal antibodies have been shown to have a negative impact on the efficacy of intranasal vaccination of calves from 2 weeks of age, therefore the efficacy of intranasal 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.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Following intranasal 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 for the person administering the veterinary medicinal product to animals

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

4.6 Adverse reactions (frequency and seriousness)

A transient slight increase in rectal temperature very commonly occurs (increase of 0.4°C following intramuscular administration and increase of 1.0°C following intranasal administration) which resolves within 4 days.
The frequency of adverse reactions is defined using the following convention:

Very common (more than 1 in 10 animals treated displaying adverse reactions)
Common (more than 1 but less than 10 animals in 100 animals treated)
Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
Rare (more than 1 but less than 10 animals in 10,000 animals treated)

Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

Fertility:

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

4.8 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.

4.9 Amount(s) to be administered and administration route

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 intranasal administration aspirate the required volume of reconstituted vaccine, (1ml 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 intranasal administration of one dose (2 ml) from 2 weeks of age.

Revaccination:

There is no information available on revaccination following intranasal 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 intranasal 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Zero days.

5.<PHARMACOLOGICAL> <IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group:

Immunologicals for Bovidae, live virus vaccines for cattle.
ATCvetcode: 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisation medium:
Tromethamine (TRIS)
Edetic acid (Chelaton II)
Sucrose
Dextran 70
Water for Injection

Solvent:
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for Injection

6.2 Incompatibilities

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

6.3 Shelf life

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

6.4 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) and do not freeze.

6.5 Nature and composition of immediate packaging

Colourless hydrolytic type I glass vials, 3ml, 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 10ml of sterile buffered saline closed with a chlorobutyl stopper and an aluminium cap.

Colourless hydrolytic type I glass vials, 10ml, 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 50ml 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 10ml solvent – 25 doses of vaccine. Outers of 5 x 5 doses.
b) Carboard box with 10 ml lyophilised vaccine and 50ml solvent – 25 doses of vaccine.

Applicators are distributed together with the vaccine and packed separately. Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited
Tullow Industrial Estate
Bunclody Road
Tullow
Carlow
R93WOD8
Ireland

8. MARKETING AUTHORISATION NUMBER

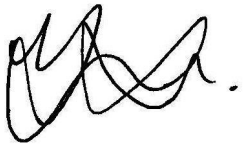
Vm 51609/4002

9. DATE OF FIRST AUTHORISATION

21 September 2021

10. DATE OF REVISION OF THE TEXT

September 2021



Approved: 21 September 2021