PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhinovac IBR Marker live

Lyophilisate and solvent for suspension for injection or nasal spray for cattle.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 2ml reconstituted vaccine contains:

Active substance

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

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection or nasal spray.

4. PACKAGE SIZE

5 x 5 doses (5 x 5 doses of lyophilised vaccine and 5 x 10ml vials of solvent.
1 x 25 doses (1 x 25 doses of lyophilised vaccine + 1 x 50ml of solvent

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose 2ml of reconstituted vaccine per animal.

Intranasal or intramuscular administration. For intranasal administration it is recommended to use the intranasal applicator.

Before use read the package leaflet.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Before use read the package leaflet.

10. EXPIRY DATE

EXP:

Shelf life after reconstitution according to directions: 8 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2˚C - 8˚C)
Protect from light
Store the reconstituted vaccine below 25˚C and do not freeze

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]
For Animal Treatment Only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 51609/4002

17. MANUFACTURER'S BATCH NUMBER

BN:

POM(E)

IE VPA 22715/…/…

Prescription Only Medicine (Exempt)

POM-V

UK Vm 51609/4002

To Be Supplied Only on Veterinary Prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhinovac IBR Marker live

Lyophilisate for suspension.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose of 2ml reconstituted vaccine contains:

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

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

5 doses

25 doses

4. ROUTE(S) OF ADMINISTRATION

Intranasal/intramuscular

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP {month/year}

Shelf life after reconstitution according to directions: 8 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

Solvent for lyophilisation of Rhinovac.

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

10ML or 50ML

3. ROUTES OF ADMINISTRATION

Read package leaflet before use

4. STORAGE

Store in a refrigerator at 2°C to 8°C

5. BATCH NUMBER

BN

6. EXPIRY DATE

EXP:

7. THE WORDS FOR ANIMAL TREATMENT ONLY

For animal treatment only

Animal Health Distributors

Tullow

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

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

Manufacturer responsible for Batch Release:

Bioveta, a.s.
Komenského 212/12
Ivanovice na Hané
683 23
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhinovac IBR Marker live

Lyophilisate and solvent for suspension for injection or nasal spray for cattle.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

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 infective dose 50%

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. INDICATION(S)

For 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.

2 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

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Refer to previous section

10. WITHDRAWAL PERIOD(S)

Zero Days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

Store in a refrigerator (2˚C - 8˚C)
Protect from light
Store the reconstituted vaccine below 25˚C (for 8 hours) and do not freeze.

12. SPECIAL WARNING(S)

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.

Vaccinate healthy animals only

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.

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 consideration of individual cases.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Xx/xx/xxxx

15. OTHER INFORMATION

Package sizes

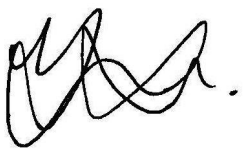
5 x 5 doses (5 x 5 doses of lyophilised vaccine + 5 x 10ml solvent)

1 x 25 doses (1 x 25 doses of lyophilsed vaccine + 1 x 50ml solvent)

Applicators are distributed with the vaccine and packed separately

Not all pack sizes may be marketed

For Animal Treatment Only



Approved: 21 September 2021