PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATE PACKAGE

BOX
Vials of 50 doses (200 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidec suspension for injection
BVD virus vaccine

2. STATEMENT OF ACTIVE ~~AND OTHER~~ SUBSTANCES

Each dose (4 ml) contains 5 x 10^6 $TCID_{50}$ of inactivated BVD virus strain KY1203nc, Quil A, Thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

6 x 5 doses (6 x 20 ml)
50 doses (200 ml)

5. TARGET SPECIES

Cattle

6. INDICATIONS

For the active immunisation of adult female breeding cattle:
1. Prior to insemination/service to prevent infection of the foetus with BVD Type I virus.
2. It has been shown under field conditions that the vaccine may reduce the incidence of herd infertility when a diagnosis of infertility is associated with clinical manifestations of BVD Type I infection.
For the active immunisation of calves from the age of 4 months:
1. To reduce viraemia and viral shedding of BVD Type I virus, once maternal antibodies have declined.
2. To reduce viraemia and the clinical signs of disease caused by BVD virus Type II, once maternal antibodies have declined.

7. METHOD AND ROUTES OF ADMINISTRATION

Administration
Shake well before use.

Administer 4 ml by subcutaneous injection. It is recommended that vaccination be performed high on the side of the neck. Syringes and needles should be sterile and the

injection made through an area of clean and dry skin observing aseptic technique.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

Do not freeze.

10. EXPIRY DATE

Expiry date:

Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Marketing authorisation holder:
Benchmark Animal Health Ltd.
Benchmark House
8 Smithy Wood Drive
Chapeltown, Sheffield
South Yorkshire
S35 1QN
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 43684/4001

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 5 doses (20 ml)

Bovidec suspension for injection for cattle
BVD virus vaccine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (4 ml) contains $5x10^6$ $TCID_{50}$ inactivated BVD virus strain KY1203nc, Quil A, Thiomersal.

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

5 doses (20 ml)

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Expiry date:
Once broached, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

OTHER INFORMATION

Store and transport refrigerated.
Do not freeze.

Marketing authorisation holder:

Benchmark Animal Health Ltd.
Benchmark House
8 Smithy Wood Drive
Chapeltown, Sheffield
South Yorkshire
S35 1QN
United Kingdom

Indications: For the active immunisation of adult female breeding cattle and calves against BVD virus.

Read the package leaflet before use.
Keep out of the reach and sight of children.

To be supplied only on veterinary prescription.

POM-V

Vm 43684/4001

PACKAGE LEAFLET:
Bovidec suspension for injection
BVD virus vaccine

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

Marketing authorisation holder:
Benchmark Animal Health Ltd.,
Benchmark House, 8 Smithy Wood Drive, Chapeltown, Sheffield, South Yorkshire, S35 1QN, United Kingdom

Manufacturer for the batch release:
Benchmark Vaccines Limited, 4 Warner Drive, Springwood Industrial Estate Braintree, Essex CM7 2YW,
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidec suspension for injection for cattle
BVD virus vaccine

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

Bovidec is a pink, aqueous suspension containing an inactivated non-cytopathic bovine viral diarrhoea (BVD) virus strain KY1203nc.

Each dose (4 ml) contains:
Active substance:
inactivated bovine viral diarrhoea (BVD) virus Strain KY1203nc (inactivated) 5×10^6 $TCID_{50}$

Adjuvant
Quil A

Excipients
Thiomersal (preservative)

4. INDICATIONS

For the active immunisation of adult female breeding cattle:
1. Prior to insemination/service to prevent infection of the foetus with BVD Type I virus. Results from studies available to date indicate that the protection afforded against BVDV Type I should exist for at least 420 days post initial vaccination.
2. It has been shown under field conditions that the vaccine may reduce the incidence of herd infertility when a diagnosis of infertility is associated with clinical manifestations of BVD Type I infection.

For the active immunisation of calves from the age of 4 months:

1. To reduce viraemia and viral shedding of BVD Type I virus, vaccinated once maternal antibodies have declined. The duration of immunity is 13 months.
2. To reduce viraemia and the clinical signs of disease caused by BVD virus Type II, vaccinated once maternal antibodies have declined. Results indicate the reduction in symptoms afforded should persist for at least 21 days following vaccination course.

5. CONTRAINDICATIONS

Animals younger than 4 months of age should not be vaccinated due to the possible interference of maternally derived antibodies with vaccine efficacy.
Do not use in cases of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.
Avoid vaccination of animals, which have intercurrent disease, are on a course of concomitant therapy or have a poor nutritional status.

6. ADVERSE REACTIONS

Occasional hypersensitivity reactions may occur as with all vaccines. Should anaphylaxis occur, use epinephrine (adrenaline).
Transient pyrexia and injection site inflammatory reactions may occur. The pyrexia is unassociated with any other clinical illness, the animals continuing to behave and eat normally. The local reaction consists of a diffuse, subcutaneous oedema, which subsides over 2-3 weeks.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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

The dose is 4 ml administered by subcutaneous injection. It is recommended that injection be made high on the side of the neck.

Primary Vaccination
Adult breeding cattle:
Animals should receive 2 doses of vaccine, 3 weeks apart. The vaccination programme should be completed not less than 7 days prior to service.

Calves:
Animals should receive 2 doses of vaccine, 3 weeks apart. Calves can be vaccinated from 3.5 months of age once maternal antibody has declined. Where calves are likely to be seropositive, the minimum age of primary vaccination should be 5 months.

Booster Vaccination
A single annual booster dose is recommended. For adult breeding cattle, booster vaccination should be administered not less than 7 days prior to service.

9. ADVICE ON CORRECT ADMINISTRATION

Syringes and needles should be sterile and the injection made through an area of clean and dry skin observing aseptic technique.

Shake the container well before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after “Expiry date:” The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
A small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reason. Satisfactory immune responses will only be attained in healthy animals. When pregnant animals are vaccinated, it should be remembered that the calves they are carrying may have already been exposed to virus if the dam was naïve in the earlier stages of pregnancy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy:
Bovidec can be administered to pregnant cattle. Administration of Bovidec during one or other of the trimester periods has demonstrated no difference in the overall outcome of pregnancy, compared with unvaccinated control animals.

Interaction with other medicinal products and other forms of interaction:
No information is available on the compatibility of this vaccine 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.

Overdose (symptoms, emergency procedures, antidotes):
The administration of an overdose via the subcutaneous route will result in marked swelling at the injection site and a transient pyrexia. The duration of the reactions is unknown but can last for at least 2 weeks and the pyrexia will resolve within 12-24 hours. No specific treatment is necessary

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist 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

15. OTHER INFORMATION

The vaccine is supplied in type 1 glass vials, closed with bromobutyl rubber stoppers and aluminium seals, and in quantities of 5 doses (20 ml) and 50 doses (200 ml.)

Not all pack sizes may be marketed.

Marketing Authorisation No.: Vm 43684/4001

To be supplied only on veterinary prescription.

POM-V

For any information about this veterinary medicinal product, contact the marketing authorisation holder/distributor:
Benchmark Animal Health Ltd.
Benchmark House
8 Smithy Wood Drive
Chapeltown, Sheffield
South Yorkshire
S35 1QN
United Kingdom

Approved: 20 June 2019

D Austin