LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis BVD-MD suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
50 ELISA Units inactivated BVDV type 1 strain C-86 inducing at least 4.6 $\log_2$ VN units

3. PACKAGE SIZE

1 dose
5 doses
10 doses
25 doses
50 doses
125 doses

4. TARGET SPECIES

Cattle (cows, heifers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3026

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS or PET VIAL of 50/125 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis BVD-MD suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
50 ELISA Units inactivated BVDV type 1 strain C-86 inducing at least 4.6 log2 VN units

50 doses
125 doses

3. TARGET SPECIES

Cattle (cows, heifers).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS or PET VIAL of 1/5/10/25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis BVD-MD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (2 ml) contains: 50 ELISA Units inact. BVDV-1 strain C-86

1 dose
5 doses
10 doses
25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bovilis BVD-MD suspension for injection for cattle

2. Composition

Each dose (2 ml) contains:

Active substance:
Inactivated antigen of cytopathogenic bovine viral diarrhoea (BVD) virus type 1 strain C-86,
containing 50 ELISA Units (EU) and inducing at least 4.6 $\log_2$ VN units*

* Mean virus neutralizing titre obtained in the potency test

Adjuvant:
Aluminium 3+ (as Al-phosphate and Al-hydroxide): 6-9 mg

Excipient:
Methyl parahydroxybenzoate: 3 mg

Red to pink-coloured turbid suspension.

3. Target species

Cattle (cows and heifers).

4. Indications for use

For active immunisation of cows and heifers from eight months of age onwards to protect the foetus against transplacental infection with bovine viral diarrhoea virus.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 the label to the physician.

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that for revaccination - in cattle from 15 months of age onwards (i.e. those that have previously been vaccinated separately with Bovilis BVD and Bovilis IBR Marker Live) - this vaccine can be mixed and administered with Bovilis IBR Marker Live (in Member States where this veterinary medicinal product is authorised). The product literature of Bovilis IBR Marker Live should be consulted before administration of the mixed products. The adverse events observed after administration of one dose or an overdose of the mixed vaccines are not different from those described for the vaccines administered separately.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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:
No adverse effects other than those mentioned in section "Adverse events" were observed after administration of a 2-fold overdose of the vaccine.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except with Bovilis IBR Marker Live (for revaccination only).

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1]. Pyrexia (fever)[2]. Hypersensitivity reaction, anaphylactic shock (severe allergic reaction)[3].

[1] Observed for 14 days.
[2] Transient and mild.
[3] Including anaphylactic shock. In the event of anaphylactic type reactions appropriate treatment with antihistamine, corticosteroid or adrenaline is recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular injection with one dose of 2 ml per animal.
All cattle can be vaccinated from an age of eight months onwards.

Foetal protection can be expected if the primary immunisation has been finalised 4 weeks before start of the gestation. Animals which are vaccinated later than 4 weeks before gestation or during the early gestation will not be protected against foetal infection.

Individual vaccination
Basic immunisation
Two vaccinations with an interval of 4 weeks. The second vaccination should be given not later than 4 weeks before the start of the gestation.
Revaccination
One vaccination 4 weeks before start of the next gestation.

Herd vaccination
Basic immunisation
Two vaccinations with an interval of 4 weeks. For use in cattle from eight months of age, all animals should be vaccinated.
Revaccination
One vaccination 6 months after basic vaccination with next revaccinations at an interval no greater than 12 months.

For revaccination, the vaccine may be used for reconstitution of Bovilis IBR Marker Live for use in cattle from 15 months of age (i.e. those that have previously been vaccinated separately with Bovilis BVD and Bovilis IBR Marker Live) and the following instructions should be used:

Bovilis IBR Marker Live		Bovilis BVD
5 doses	+	10 ml
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml

A single dose (2 ml) of Bovilis BVD mixed with Bovilis IBR Marker Live is given intramuscularly.
The product literature of Bovilis IBR Marker Live should be consulted before administration of the mixed products.

9. Advice on correct administration

Before using the vaccine allow it to reach ambient temperature (15 °C – 25 °C).
Shake well before use. Use sterile syringes and needles.

Visual appearance after reconstitution of Bovilis IBR Marker Live in Bovilis BVD:
As specified for Bovilis BVD alone.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (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 Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Bovilis IBR Marker Live: 3 hours (at room temperature).

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

[AT, BE, DE, EL, ES, FR, IT, LU, NL, PL, PT, SI, SK, UK(XI):] Veterinary medicinal product subject to prescription.

[IE:] Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3026

Pack sizes:
Cardboard box containing 1 glass or plastic vial of 2 ml (1 dose)
Cardboard box containing 1 glass or plastic vial of 10 ml (5 doses)
Cardboard box containing 1 glass or plastic vial of 20 ml (10 doses)
Cardboard box containing 1 glass or plastic vial of 50 ml (25 doses)
Cardboard box containing 1 glass or plastic vial of 100 ml (50 doses)
Cardboard box containing 1 glass or plastic vial of 250 ml (125 doses)

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
UK(NI): Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

This vaccine is an inactivated vaccine containing 50 ELISA Units inducing at least 4.6 $\log_2$ VN units per dose of cytopathogenic BVD virus type 1 strain C-86. The virus is grown in cell cultures and is inactivated with beta-propiolactone. The antigen is adsorbed onto an aluminium salts adjuvant. The vaccine contains methyl parahydroxy-benzoate as a preservative and traces of antibiotics and calf serum as remnants from the antigen production.

{to be completed nationally}

Gavin Hall
Approved: 10 January 2025