1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis BVD suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance:
Inactivated 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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate	3 mg
Propylene glycol	
Tromethamine	
Tissue culture medium	
Hydrochloric acid solution or tromethamine solution	
Water for injections	

Red to pink-coloured turbid suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows and heifers).

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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**.**

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

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

[1] Observed for 14 days.
[2] Transient and mild.
[3] 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative 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:
Can be used during pregnancy.

3.8 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.

3.9 Administration routes and dosage

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

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

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

No adverse effects other than those mentioned in section 3.6 were observed after administration of a 2-fold overdose of the vaccine.

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: QI02AA01.

This vaccine is an adjuvanted aqueous inactivated viral vaccine for active immunisation of cows and heifers against transplacental infection with bovine viral diarrhoea virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing with Bovilis IBR Marker Live: 3 hours (at room temperature).

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

Vials of glass (hydrolytic type I, Ph. Eur.) or plastic (polyethylene-terephthalate, PET) closed with a rubber (halogenobutyl) stopper and an aluminium cap.

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.

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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/271/001

8. DATE OF FIRST AUTHORISATION

30/08/1999

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

09/02/2024

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).