PACKAGE LEAFLET:

Bovilis BVD
Suspension for injection for cattle

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

Marketing authorisation holder:
The national representative of
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis BVD
(DE: Bovilis BVD-MD)
Suspension for injection for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Red to pink-coloured turbid suspension.

Each dose of 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

Excipients:
Methyl parahydroxybenzoate: 3 mg (preservative)

4. INDICATION(S)

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. ADVERSE REACTIONS

In very rare cases a slight swelling may be observed for 14 days at the site of injection. Also in very rare cases transient mild pyrexia may occur. In very rare cases, hypersensitivity reactions including anaphylactic shock may occur. In the event of anaphylactic type reactions, appropriate treatment such as with antihistamine, corticosteroid or adrenaline is recommended.

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 serious 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 (cows, heifers).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

<u>Individual vaccination</u>
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.

<u>Herd vaccination</u>
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 re-vaccinations 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 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). Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 10 hours.
Shelf life after mixing with Bovilis IBR marker live: 3 hours (at room temperature).

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the 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 re-vaccination -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 effects 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 (symptoms, emergency procedures, antidotes):
Reactions after a double dose are not different from those after the single dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except with Bovilis IBR marker live (for revaccination only).

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

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

{MM/YYYY}

15. OTHER INFORMATION

Bovilis BVD 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 parahydroxybenzoate as a preservative and traces of antibiotics and calf serum as remnants from the antigen production.

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

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

Not all pack sizes may be marketed.

For animal treatment only.
Veterinary medicinal product subject to prescription.
(*Comment:may be replaced by national wording and/or symbol)*

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.