Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIDEC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (4 ml) contains:

Active Substance:

Bovine Viral Diarrhoea (BVD) virus strain KY1203nc (inactivated)	5 x 106 TCID50*	

*TCID50 = 50% Tissue culture infectious dose

Adjuvant:

Quil A	1.0	mg

Excipient:

Thiomersal (preservative)	0.044 – 0.060	mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.
A pink aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.
Female breeding cattle and calves from 4 months of age.

4.2 Indications for use, specifying the target species

(i) Adult female breeding cattle

For the active immunisation of female breeding cattle:
1. Prior to insemination/service to protect the foetus against infection with BVD Type I virus.
2. Prior to service in the management of herd fertility when diagnosis of infertility is associated with clinical manifestations of BVD Type I virus infection.

(ii) Calves

The vaccine is also for the active immunisation of calves to reduce infection with BVD Type I virus. Animals younger than 4 months of age should not be vaccinated due to the possible interference of maternally derived antibodies with vaccine efficacy once maternal antibodies have declined.

Results from calf studies to date indicate antibodies are detectable 28 days after completion of the initial vaccination procedure and protection has been demonstrated at 42 days after completion of the initial vaccination procedure.The active protection afforded by vaccination of calves against Type I should exist for at least 420 days post the initial calf vaccination procedure.

The vaccine also affords cross protection against Bovine Viral Diarrhoea Virus Type II infection, with reduction of viraemia and clinical signs of disease being observed in animals vaccinated when maternal antibodies have declined.Results indicate the reduction in symptoms afforded should exist for at least 21 days following vaccination course.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.
Avoid vaccination of animals that have intercurrent disease, are on a course of concomitant therapy or have a poor nutritional status.

4.4 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. Vaccination in the presence of maternally derived antibodies may reduce the efficacy of the vaccine. 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. The primary vaccination course must be completed before service/ insemination, as an aid in the protection of the foetus from the time of conception. Only farms with sub-optimal fertility associated with BVDV infection will benefit from BVDV vaccination. No overall improvement in fertility will be observed in farms attaining expected levels of fertility.

The product will not be effective in conferring foetal protection in the face of Type II BVDV infection.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

None.

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.

4.6 Adverse reactions (frequency and seriousness)

Occasional hypersensitivity reactions may occur. These may include swelling of the vulva/vagina, nose or eyelids.
Should systemic anaphylaxis occur, use epinephrine (adrenaline).
Transient pyrexia and injection site inflammatory reactions may occur following injection. Transient pyrexia of up to 41.1 °C (increases < 2^{o}C) has been observed in up to 70% of animals for up to 48 hours after injection. The pyrexia is unassociated with any other clinical illness, the animals continuing to behave and eat normally. Mild to moderate localised pain may occur in up to 40% of animals, which resolve in the majority of animals after 3 days. Transient local swellings (up to 42 mm) are seen in up to 100% of animals after each vaccination. These swellings resolve in the majority of animals over 2-3 weeks.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

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 therefore needs to be decided on a case by case basis.

4.9 Amounts to be administered and administration route

To be used in female breeding cattle and calves. The dose is 4 ml administered by subcutaneous injection. It is recommended that vaccination be made high on the side of the neck. Syringes and needles should be sterile and the injection made through an area of clean, dry skin taking precautions against contamination. Shake the container well before withdrawing the dose.

Primary Vaccination
Animals should receive 2 doses of vaccine separated by a 3 week interval. For adult breeding cattle the vaccination programme should be completed not less than 7 days prior to service. Calves can be vaccinated from 4 months of age once maternal antibody has declined.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The administration of an overdose via the subcutaneous route will result in marked swelling at the injection site and a transient pyrexia. Transient local swellings (up to 42 mm) are seen in up to 100% of animals and will resolve over the following two to three weeks without permanent sequelae. Transient pyrexia of up to 41.7 °C (increases < 2^{o}C) have been observed in up to 80% of animals and will resolve within 12-24 hours.No specific treatment is necessary.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, cattle, inactivated viral vaccines: bovine viral diarrhea (BVD).
ATC Vet Code: Q102AA01To induce active immunity against BVDV in the target species.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quil A
Thiomersal
Minimum Essential Medium

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the 20 ml presentation as packaged for sale: 18 months.
Shelf-life of the 200 ml presentation as packaged for sale: 12 months.
Shelf-life after first opening the immediate packaging: Use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2°C - 8°C).
Do not freeze.

6.5 Nature and composition of immediate packaging

Container: 20 ml, Type I, clear glass vial.
Closure: Bromobutyl bung with aluminium overseal
Outer Pack: Cardboard Box with insert leaflet
Pack size: 6 x 5 doses (6 x 20 ml vials).

Container: 200 ml Type I, clear glass vial
Closure: Bromobutyl bung with aluminium overseal
Outer Pack: Cardboard carton with insert leaflet
Pack size single 50 dose (200 ml vial).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Benchmark Animal Health Norway AS (trading as Benchmark Animal Health)
Sandviksbodene 3A
5035 Bergen
Norway

8 MARKETING AUTHORISATION NUMBER(S)

VPA22980/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 August 2000
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

March 2020