SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovidec suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (4 ml) contains:

Active substance:

bovine viral diarrhoea (BVD) virus strain KY1203nc (inactivated)	5×10^6 $TCID_{50}$.

Adjuvant:

Quil A	1 mg.

Excipients:
Thiomersal.

For the full list of excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Pink, aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use (specifying the target species)

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, 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, once maternal antibodies have declined. Results indicate the reduction in symptoms afforded should persist for at least 21 days after vaccination.

4.3 Contraindications

Do not administer to animals that have previously shown a hypersensitivity reaction.

Avoid vaccination of animals, which have intercurrent disease, are on a course of concomitant therapy or have a poor nutritional status.

4.4 Special warnings (for each target species)

In any group of animals, 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 might have already been exposed to virus if the dam was naïve in the earlier stages of pregnancy.

4.5 Special precautions for use

(i) Special precautions for use in animals
None.

(ii) Special precautions to be taken by the person administering the product to animals
Care should be taken to avoid self-injection: if this occurs, seek medical advice and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy and lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore, the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amount(s) to be administered and administration route

The dose is 4 ml administered by subcutaneous injection. It is recommended that injection be made 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.
Shake the container well before use.

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.

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. 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, cattle, inactivated viral vaccines.
ATCvet code: QI02AA01.

To induce active immunity against BVDV in the target species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quil A
Thiomersal
Minimal Essential Medium

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 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 the immediate packaging

Box with 6 x 5 dose (6 x 20 ml) vials:
Container: clear Type I glass vial.
Closure: bromobutyl rubber stopper with aluminium overseal.
Outer pack: cardboard box with inserted package leaflet.

Box with single 50 dose (200 ml) vial:
Container: clear type I glass vial.
Closure: bromobutyl rubber stopper with aluminium overseal.
Outer pack: cardboard box with inserted package leaflet.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 43684/4001

9. DATE OF FIRST AUTHORISATION

22 September 1995

10. DATE OF REVISION OF THE TEXT

June 2019

Approved: 20 June 2019