SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Lyophilisate:
Active substances:
Modified live BVDV*-1, non-cytopathic parent strain KE-9: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**,
Modified live BVDV*-2, non-cytopathic parent strain NY-93: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**.

* Bovine viral diarrhoea virus
** Tissue culture infectious dose 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: off-white colour without foreign matter.
Solvent: clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For active immunisation of cattle from 3 months of age to reduce hyperthermia and to minimise the reduction of leukocyte count caused by bovine viral diarrhoea virus (BVDV-1 and BVDV-2), and to reduce virus shedding and viraemia caused by BVDV-2.

For active immunisation of cattle against BVDV-1 and BVDV-2, to prevent the birth of persistently infected calves caused by transplacental infection.

Onset of immunity: 3 weeks after immunisation.
Duration of immunity: 1 year after immunisation.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

Long lasting viremia has been observed after vaccination, in particular in pregnant seronegative heifers (10 days in a study). This may result in transplacental transmission of the vaccine virus, but no adverse effects on foetus or pregnancy was observed in studies.

Shedding of the vaccine virus by body fluids cannot be excluded.
The vaccine strains are able to infect sheep and swine when administered intranasally, but no adverse reactions or spreading to in-contact animals has been demonstrated.
The vaccine has not been tested in breeding bulls and should therefore not be used in breeding bulls.

4.5 Special precautions for use

i) Special precautions for use in animals

Vaccinate healthy animals only.
To ensure the protection of animals introduced to the herd where BVDV is circulating, vaccination has to be completed 3 weeks before introduction.

The cornerstone of bovine viral diarrhoea (BVD)-eradication is identification and culling of persistently infected animals. A definitive diagnosis of persistent infection can only be established upon re-testing in blood after an interval of at least 3 weeks. In some limited cases with newborn calves, positive ear notches for BVDV vaccine strain were reported by molecular diagnostic tests. Additional laboratory tests to differentiate vaccine strain virus from field strain are available upon request from the marketing authorisation holder.

The field studies to investigate the efficacy of the vaccine were done in herds where persistently infected animals had been removed.

ii) 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.

4.6 Adverse reactions (frequency and seriousness)

Target species: cattle

Common (1 to 10 animals / 100 animals treated):	Elevated temperature*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling or Injection site nodule** Hypersensitivity reaction including anaphylactic-type reaction.

*within the physiological range is common within 4 hours of vaccination, resolving within 24 hours**≤ 3 cm in diameter, resolving within 4 days after vaccination

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 the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
It is recommended to vaccinate before pregnancy to ensure protection against persistent infection of the foetus. While persistent infection of the foetus caused by the vaccine was not observed, transmission of vaccine virus to the foetus may occur. Therefore, use during pregnancy should only be on a case-by-case basis decided by the responsible veterinarian, taking into consideration e.g. the BVD immunological status of the animal, the time-span between vaccination and mating/insemination, the stage of pregnancy and the risk of infection.

Can be used during lactation.
Studies have shown that vaccine virus may be excreted in milk up to 23 days after vaccination at low amounts (~ 10 $TCID_{50}$/ml), although when such milk was fed to calves, no seroconversion occurred in those calves.

4.8 Interaction with other medicinal products and other forms of interaction

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 made on a case by case basis.

4.9 Amount(s) to be administered and administration route

Intramuscular use.

Preparation of vaccine for use (reconstitution):
Reconstitute the lyophilisate by adding the full content of the solvent at room temperature.
Ensure that the lyophilisate is completely reconstituted before use.
The reconstituted vaccine is transparent and colourless.
Avoid multiple broaching.

Primary vaccination:
After reconstitution, administer one dose (2 ml) of the vaccine by intramuscular (IM) injection.
It is recommended to vaccinate cattle at least 3 weeks before insemination/mating to provide foetal protection from the first day of conception. Animals which are vaccinated later than 3 weeks before gestation or during the early gestation may not be protected against foetal infection. This should be considered in case of herd vaccination.

Recommended re-vaccination programme:
Revaccination is recommended after 1 year.
12 months after primary vaccination most studied animals still had antibody titres at plateau while some animals had lower titres.

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

Mild swellings or nodules up to 3 cm diameter were observed at the injection site after administration of a 10-fold overdose and disappeared within 4 days post vaccination.

Furthermore, an increase of the rectal body temperature was common within 4 hours following administration and spontaneously resolves within 24 hours (see section 4.6).

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, live viral vaccines

ATC Vet Code: QI02AD02

The vaccine is designed to stimulate the development of an active immune response against BVDV-1 and BVDV-2 in cattle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sucrose
Gelatine
Potassium hydroxide
L-Glutamine acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Water for injections

Solvent:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

6.3 Shelf life

Lyophilisate:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Solvent:
Shelf life of the solvent: 3 years.

Shelf life after reconstitution according to directions: 8 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the lyophilisate and the solvent vials in the outer carton.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I amber glass vials closed with siliconised bromobutyl rubber stopper with lacquered aluminium seal.

Solvent:
High density polyethylene (HDPE) bottles of solvent, closed with a siliconised chlorobutyl rubber stopper with lacquered aluminium seal.

1 lyophilisate vial of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 1 solvent bottle of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

4 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 4 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

6 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 6 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

10 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 10 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5004

9. DATE OF FIRST AUTHORISATION

22 December 2014

10. DATE OF REVISION OF THE TEXT

February 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant country's competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 17 February 2023