PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box: 5 doses, 10 doses, 25 doses, 50 doses lyophilisate and 10 ml, 20 ml, 50 ml, 100 ml solvent}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) contains:
Bovine viral diarrhoea virus type 1: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$,
Bovine viral diarrhoea virus type 2: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$.

3. PACKAGE SIZE

5 doses (10 ml)
10 doses (20 ml)
25 doses (50 ml)
50 doses (100 ml)
4 x 5 doses (10 ml)
4 x 10 doses (20 ml)
4 x 25 doses (50 ml)
4 x 50 doses (100 ml)
6 x 5 doses (10 ml)
6 x 10 doses (20 ml)
6 x 25 doses (50 ml)
6 x 50 doses (100 ml)
10 x 5 doses (10 ml)
10 x 10 doses (20 ml)
10 x 25 doses (50 ml)
10 x 50 doses (100 ml)

4. TARGET SPECIES

Cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp {dd/mm/yyyy}

Once reconstituted use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the vials in the outer carton

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/5004

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V ('To be supplied only on veterinary prescription')

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Lyophilisate vials: 50 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate for suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) contains:
BVDV-1: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$,
BVDV-2: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$.

50 doses (100 ml)

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

IM
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp {dd/mm/yyyy}

Once reconstituted use within: 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the vial in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V ('To be supplied only on veterinary prescription')

15. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5004

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Lyophilisate vials: 5 doses, 10 doses and 25 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

BVDV-1 BVDV-2
5 ds
10 ds
25 ds

10 ml
20 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {dd/mm/yyyy}
Once reconstituted use within: 8 hours.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

1. NAME OF THE DILUENT/SOLVENT

Solvent for Bovela

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml
50 ml
100 ml

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated.
Keep the bottle in the outer carton.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp {dd/mm/yyyy}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle

2. COMPOSITION

Each dose (2 ml) contains:

Lyophilisate:
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%

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

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

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.

Special precautions for safe use in the 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 occurred.
The vaccine has not been tested in breeding bulls and should therefore not be used in breeding bulls.

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.

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.

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.

Overdose:
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 “Adverse events”).

Special restrictions for use and special conditions for 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.

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

7. ADVERSE EVENTS

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 reactions, including anaphylactic-type reactions.

*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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the vials in the outer carton.
Shelf life after reconstitution: 8 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after the abbreviation Exp.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 04491/5004

Package sizes:
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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

{MM/YYYY}

16. CONTACT DETAILS

Marketing authorisation holder
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Boehringer Ingelheim Animal Health France SCS, Laboratoire Porte des Alpes,
Rue de l'Aviation,
69800 Saint-Priest
FRANCE

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Tel: + 44 1344 746957

17. OTHER INFORMATION

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

For Animal Treatment Only.

Approved 17 February 2023