

**ANNEX I**

**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<sub>50</sub>\*\*,

Modified live BVDV\*-2, non-cytopathic parent strain NY-93:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>\*\*.

\* Bovine viral diarrhoea virus

\*\* Tissue culture infectious dose 50%

### Excipients:

Qualitative composition of excipients and other constituents
<b><i>Lyophilisate:</i></b>
Sucrose
Gelatine
Potassium hydroxide
L-Glutamine acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Water for injections
<b><i>Solvent:</i></b>
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injections

Lyophilisate: off-white colour without foreign matter.

Solvent: clear, colourless solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle

### **3.2 Indications for use for each 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.

### **3.3 Contraindications**

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

### **3.4 Special warnings**

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.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

Longlasting 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.

#### 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.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 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 reaction including anaphylactic-type reaction.

\* within physiological range, within 4 hours from 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.

### 3.7 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<sub>50</sub>/ml), although when such milk was fed to calves, no seroconversion occurred in those calves.

### 3.8 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.

### 3.9 Administration routes and dosage

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.

**3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)**

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 3.6).

**3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

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.

**3.12 Withdrawal periods**

Zero days.

**4. IMMUNOLOGICAL INFORMATION**

**4.1 ATCvet code: QI02AD02**

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

**5. PHARMACEUTICAL PARTICULARS**

**5.1 Major incompatibilities**

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

**5.2 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.

### **5.3 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.

### **5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH

## **7. MARKETING AUTHORISATION NUMBER(S)**

EU/2/14/176/001-016

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 22.12.2014

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{DD/MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **ANNEX II**

### **OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

None



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**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 SUBSTANCES**

Each dose (2 ml) contains:

Bovine viral diarrhoea virus type 1:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>,

Bovine viral diarrhoea virus type 2:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>.

**3. PACKAGE SIZES**

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. INDICATIONS****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 OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH

**14. MARKETING AUTHORISATION NUMBERS**

EU/2/14/176/001 5 doses and 10 ml  
EU/2/14/176/002 5 doses and 10 ml (4 x)  
EU/2/14/176/003 5 doses and 10 ml (6 x)  
EU/2/14/176/004 5 doses and 10 ml (10 x)  
EU/2/14/176/005 10 doses and 20 ml  
EU/2/14/176/006 10 doses and 20 ml (4 x)  
EU/2/14/176/007 10 doses and 20 ml (6 x)  
EU/2/14/176/008 10 doses and 20 ml (10 x)  
EU/2/14/176/009 25 doses and 50 ml  
EU/2/14/176/010 25 doses and 50 ml (4 x)  
EU/2/14/176/011 25 doses and 50 ml (6 x)  
EU/2/14/176/012 25 doses and 50 ml (10 x)  
EU/2/14/176/013 50 doses and 100 ml  
EU/2/14/176/014 50 doses and 100 ml (4 x)  
EU/2/14/176/015 50 doses and 100 ml (6 x)  
EU/2/14/176/016 50 doses and 100 ml (10 x)

<b>15. BATCH NUMBER</b>
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Lot {number}

**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 SUBSTANCES**

Each dose (2 ml) contains:

BVDV-1:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>,BVDV-2:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>.

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}

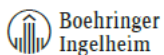
Once reconstituted use within: 8 hours.

**7. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Keep the vial in the outer carton.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

<b>9. BATCH NUMBER</b>
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Lot {number}

**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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

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.



**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT**

**Solvent bottles: 10 ml, 20 ml, 50 ml, 100 ml**

**1. NAME OF THE DILUENT**

Solvent for Bovela

**2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10 ml  
20 ml  
50 ml  
100 ml

**3. ROUTE(S) 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.



## **B. PACKAGE LEAFLET**

## 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<sub>50</sub>\*\*,

Modified live BVDV\*-2, non-cytopathic parent strain NY-93:  $10^{4.0}$ – $10^{6.0}$  TCID<sub>50</sub>\*\*.

\* 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 warnings

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:

Longlasting 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<sub>50</sub>/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 marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes 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 periods

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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist 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**

EU/2/14/176/001 - EU/2/14/176/016

### 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}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **16. Contact details**

### Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH  
55216 Ingelheim/Rhein  
GERMANY

### Manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH  
55216 Ingelheim/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:

#### **België/Belgique/Belgien**

Boehringer Ingelheim Animal Health Belgium SA  
Tél/Tel: + 32 2 773 34 56

#### **Lietuva**

Boehringer Ingelheim RCV GmbH & Co KG  
Lietuvos filialas  
Tel: +370 5 2595942

#### **Република България**

Boehringer Ingelheim RCV GmbH & Co KG  
Tel: +359 2 958 79 98

#### **Luxembourg/Luxemburg**

Boehringer Ingelheim Animal Health Belgium SA  
Tél/Tel: + 32 2 773 34 56

#### **Česká republika**

Boehringer Ingelheim spol. s r.o.  
Tel: +420 234 655 111

#### **Magyarország**

Boehringer Ingelheim RCV GmbH & CoKG  
Magyarországi Fióktelep  
Tel: +36 1 299 8900

#### **Danmark**

Boehringer Ingelheim Animal Health Nordics A/S  
Tlf: + 45 3915 8888

#### **Malta**

Boehringer Ingelheim Animal Health UK Limited  
Tel: +44 1344 746957

#### **Deutschland**

Boehringer Ingelheim Vetmedica GmbH  
Tel: 0800 290 0 270

#### **Nederland**

Boehringer Ingelheim Animal Health  
Netherlands bv  
Tel: +31 20 799 6950

#### **Eesti**

Boehringer Ingelheim RCV GmbH & Co KG  
Eesti filiaal  
Tel: +372 612 8000

#### **Norge**

Boehringer Ingelheim Animal Health Nordics A/S  
Tlf: +47 66 85 05 70

#### **Ελλάδα**

Boehringer Ingelheim Vetmedica GmbH  
Τηλ: +30 2108906300

#### **Österreich**

Boehringer Ingelheim RCV GmbH & Co KG  
Tel: +43 1 80105-6880

#### **España**

Boehringer Ingelheim Animal Health España,  
S.A.U.  
Tel: +34 93 404 51 00

#### **Polska**

Boehringer Ingelheim Sp. z o.o.  
Tel.: + 48 22 699 0 699

**France**

Boehringer Ingelheim Animal Health France, SCS  
Tél: +33 4 72 72 30 00

**Portugal**

Boehringer Ingelheim Animal Health Portugal,  
Unipessoal, Lda.  
Tel: +351 21 313 5300

**Hrvatska**

Boehringer Ingelheim RCV GmbH & Co KG  
Tel: +385 1 2444 600

**România**

Boehringer Ingelheim RCV GmbH & Co KG  
Viena - Sucursala București  
Tel: +40 21 302 28 00

**Ireland**

Boehringer Ingelheim Animal Health UK Limited  
Tel: +353 1 291 3985

**Slovenija**

Boehringer Ingelheim RCV GmbH & Co KG  
Podružnica Ljubljana  
Tel: +386 1 586 40 00

**Ísland**

Vistor hf.  
Sími: + 354 535 7000

**Slovenská republika**

Boehringer Ingelheim RCV GmbH & Co KG, o.z.  
Tel: +421 2 5810 1211

**Italia**

Boehringer Ingelheim Animal Health Italia S.p.A.  
Tel: +39 02 53551

**Suomi/Finland**

Vetcare Oy  
Puh/Tel: + 358 201443360

**Κύπρος**

Boehringer Ingelheim Vetmedica GmbH  
Τηλ: +30 2108906300

**Sverige**

Boehringer Ingelheim Animal Health Nordics A/S  
Tlf: +46 (0)40-23 34 00

**Latvija**

Boehringer Ingelheim RCV GmbH & Co KG  
Latvijas filiāle  
Tel: +371 67 240 011

**United Kingdom (Northern Ireland)**

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.