ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Nasalgen-C nasal spray, lyophilisate and solvent for suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) of reconstituted vaccine contains:

Active substance:
Live attenuated bovine coronavirus, strain CA25: 5.4 – 7.8 $\log_{10}$ $TCID_{50}$*

*Tissue culture infectious dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate
Veggie medium
Hydrolysed gelatin
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate
Solvent (Unisolve)
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Sucrose
Water for injections

Lyophilisate: white or off-white colour.
Solvent: clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus.

Onset of immunity: 5 days.
Duration of immunity: 12 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Animals should preferably be vaccinated at least 5 – 7 days before a period of stress or increased infection pressure.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated cattle may excrete the vaccine strain nasally or orally following vaccination. Excretion has been observed for up to 9 days following vaccination but may persist longer. The vaccine strain can spread to other cattle. Spread to other species has not been investigated and cannot be excluded.
It is recommended to vaccinate all calves of the herd.

Appropriate biosecurity procedures to limit the risk of introduction and spread of bovine coronavirus infection in premises should be part of management tools.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Nasal discharge, Increased respiratory rate, Cough Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Ocular discharge

[1] Elevated temperature up to 40.7 °C which normally resolves within three days.

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 section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis INtranasal RSP Live. The vaccines should be given into different nostrils. The product information of that veterinary medicinal product should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above.
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

Nasal use.

Administer a single dose of 2 ml reconstituted vaccine to the calf from the day of birth onwards in one nostril.

Reconstitute the lyophilisate with the solvent (Unisolve) supplied as described below. Ensure that the lyophilisate is completely reconstituted before use.
The reconstituted product is a colourless or off-yellow suspension.

Instructions for reconstitution:
For proper reconstitution of the lyophilisate, transfer the solvent to the vial with the lyophilisate using a transfer needle or using a needle and syringe.

The 10-, 20-, and 50-dose presentations require a two-step reconstitution of the solvent to the vial with the lyophilisate and back to the solvent vial.
See the table below for the appropriate volumes. The vacuum in the vaccine vial will allow quick insertion of the solvent into the lyophilisate vial. Ensure complete resuspension by shaking the vial. The vaccine suspension can be drawn up in a syringe with a clean tip. Alternatively, the vial with reconstituted vaccine can be put in a multi-dose applicator.
The vaccine is now ready for administration into the nostril, directly from the tip of the syringe or applicator. A spraying device is not required.

When vaccinating animals, it is recommended to change syringes or tips of a multi-dose applicator between animals to avoid transmission of pathogens.

Doses per vial	Solvent volume required	Dose volume
1	2 ml	2 ml
5	10 ml	2 ml
10	20 ml	2 ml
20	40 ml	2 ml
50	100 ml	2 ml

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

No adverse events other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the vaccine.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AD10

The vaccine stimulates active immunity against bovine coronavirus.

The vaccine stimulates gene expression for receptors and cytokines in anti-viral innate immune responses.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 2 years.
Solvent (2 ml): 3 years.
Solvent (10, 20, 40, 100 ml): 5 years.

Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C if stored independently from the lyophilisate.
Do not freeze.

Reconstituted vaccine:
Store at room temperature.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial with 1, 5, 10, 20, or 50 doses closed with a halogenobutyl rubber stopper and aluminium cap.

Solvent:
Type I glass vial with 2 ml Unisolve closed with a halogenobutyl rubber stopper and aluminium cap.
Type II glass vial with 10 ml, 20 ml, 40 ml or 100 ml Unisolve closed with a halogenobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with:
- 1 dose of lyophilisate + 2 ml solvent
- 5 doses of lyophilisate + 10 ml solvent
- 10 doses of lyophilisate + 20 ml solvent
- 5 x 1 dose of lyophilisate + 5 x 2 ml solvent
- 5 x 5 doses of lyophilisate + 5 x 10 ml solvent
- 5 x 10 doses of lyophilisate + 5 x 20 ml solvent

- Cardboard box with 20 doses of lyophilisate + cardboard box with 40 ml solvent
- Cardboard box with 50 doses of lyophilisate + cardboard box with 100 ml solvent

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBERS

EU/2/23/294/001-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 31/03/2023.

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

{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 (https://medicines.health.europa.eu/veterinary).

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

BOX
Cardboard box with 1 dose of lyophilisate + 2 ml solvent
Cardboard box with 5 doses of lyophilisate + 10 ml solvent
Cardboard box with 10 doses of lyophilisate + 20 ml solvent
Cardboard box with 5 x 1 dose of lyophilisate + 5 x 2 ml solvent
Cardboard box with 5 x 5 doses of lyophilisate + 5 x 10 ml solvent
Cardboard box with 5 x 10 doses of lyophilisate + 5 x 20 ml solvent
Cardboard box with 1 x 20 doses of lyophilisate
Cardboard box with 1 x 50 doses of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Nasalgen-C nasal spray, lyophilisate and solvent for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated bovine coronavirus, strain CA25: 5.4 – 7.8 $\log_{10}$ $TCID_{50}$/dose

3. PACKAGE SIZE

1 dose of lyophilisate + 2 ml solvent	(1 dose)
5 doses of lyophilisate + 10 ml solvent	(5 doses)
10 doses of lyophilisate + 20 ml solvent	(10 doses)
5 x 1 dose of lyophilisate + 5 x 2 ml solvent	(5 x 1 dose)
5 x 5 doses of lyophilisate + 5 x 10 ml solvent	(5 x 5 doses)
5 x 10 doses of lyophilisate + 5 x 20 ml solvent	(5 x 10 doses)
20 doses of lyophilisate (+ 40 ml solvent)	(20 doses)
50 doses of lyophilisate (+ 100 ml solvent)	(50 doses)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
Reconstituted vaccine can be stored at room temperature.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/294/001 (1 dose)
EU/2/23/294/002 (5 doses)
EU/2/23/294/003 (10 doses)
EU/2/23/294/004 (5 x 1 dose)
EU/2/23/294/005 (5 x 5 doses)
EU/2/23/294/006 (5 x 10 doses)
EU/2/23/294/007 (20 doses)
EU/2/23/294/008 (50 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (solvent only)
Cardboard box with 40 ml solvent vial
Cardboard box with 100 ml solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Unisolve
Solvent for Bovilis Nasalgen-C

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

40 ml (20 doses)
100 ml (50 doses)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C if stored independently from the lyophilisate.
Do not freeze.
Protect from light.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/294/007 (20 doses)
EU/2/23/294/008 (50 doses)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL – Lyophilisate (vial of 1, 5, 10, 20 or 50 dose(s))
GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Nasalgen-C

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
5 doses
10 doses
20 doses
50 doses

Live attenuated bovine coronavirus: 5.4 – 7.8 $\log_{10}$ $TCID_{50}$/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 24 hours.

PARTICULARS TO APPEAR ON IMMEDIATE VIAL LABEL OF THE SOLVENT

VIAL LABEL – Solvent (vial with 2 ml, 10 ml, 20 ml, 40 ml or 100 ml)
GLASS VIAL

1. NAME OF THE SOLVENT

Unisolve
Solvent for Bovilis Nasalgen-C

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

2 ml	(1 dose)
10 ml	(5 doses)
20 ml	(10 doses)
40 ml	(20 doses)
100 ml	(50 doses)

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet.

4. STORAGE CONDITIONS

Store below 25 °C. Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {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

Bovilis Nasalgen-C nasal spray, lyophilisate and solvent for suspension for cattle

2. Composition

Each dose (2 ml) of reconstituted vaccine contains:
Live attenuated bovine coronavirus, strain CA25: 5.4 – 7.8 $\log_{10}$ $TCID_{50}$*

*Tissue culture infectious dose 50%

Lyophilisate: white or off-white colour.
Solvent: clear colourless solution.

3. Target species

Cattle.

4. Indications for use

For the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus.

Onset of immunity: 5 days.
Duration of immunity: 12 weeks

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Animals should preferably be vaccinated at least 5 – 7 days before a period of stress or increased infection pressure.

Special precautions for safe use in the target species:
Vaccinated cattle may excrete the vaccine strain nasally or orally following vaccination. Excretion has been observed for up to 9 days following vaccination but may persist longer. The vaccine strain can spread to other cattle. Spread to other species has not been investigated and cannot be excluded.
It is recommended to vaccinate all calves of the herd.

Appropriate biosecurity procedures to limit the risk of introduction and spread of bovine coronavirus infection in premises should be part of management tools.

Pregnancy and lactation:
Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered immediately before or after administration of Bovilis INtranasal RSP Live. 2 ml (1 dose) of each vaccine is administered (each vaccine into a different nostril). The product information of that veterinary medicinal product should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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:
No adverse events other than those mentioned in section 'Adverse events' were observed after administration of a 10-fold overdose of the vaccine.

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

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Nasal discharge, Increased respiratory rate, Cough Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Ocular discharge

[1]Elevated temperature up to 40.7 °C which normally resolves within three days.

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: {national system details}.

8. Dosage for each species, routes and method of administration

Nasal use.

Administer a single dose of 2 ml reconstituted vaccine to the calf from the day of birth onwards in one nostril.

Reconstitute the lyophilisate with the solvent (Unisolve) supplied as described below. Ensure that the lyophilisate is completely reconstituted before use.

Doses per vial	Solvent volume required	Dose volume
1	2 ml	2 ml
5	10 ml	2 ml
10	20 ml	2 ml
20	40 ml	2 ml

50	100 ml	2 ml

9. Advice on correct administration

Instructions for reconstitution:
For proper reconstitution of the lyophilisate, transfer the solvent (Unisolve) to the vial with the lyophilisate using a transfer needle or using a needle and syringe.

The 10-, 20-, and 50-dose presentations require a two-step reconstitution of the solvent to the vial with the lyophilisate and back to the solvent vial.
See the table above for the appropriate volumes. The vacuum in the vaccine vial will allow quick insertion of the solvent into the lyophilisate vial. Ensure complete resuspension by shaking the vial. The vaccine suspension can be drawn up in a syringe with a clean tip. Alternatively, the vial with reconstituted vaccine can be put in a multi-dose applicator.
The vaccine is now ready for administration into the nostril, directly from the tip of the syringe or applicator. A spraying device is not required.

When vaccinating animals, it is recommended to change syringes or tips of a multi-dose applicator between animals to avoid transmission of pathogens.

The reconstituted product is a colourless or off-yellow suspension.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.
Solvent: Store below 25 °C if stored independently from the lyophilisate. Do not freeze.

Shelf life after reconstitution according to directions: 24 hours. Reconstituted vaccine can be stored at room temperature.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'Exp.'. The expiry date refers to the last day of that month.

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/2/23/294/001-008

Pack sizes:
Cardboard box with:
- 1 dose of lyophilisate + 2 ml solvent
- 5 doses of lyophilisate + 10 ml solvent
- 10 doses of lyophilisate + 20 ml solvent
- 5 x 1 dose of lyophilisate + 5 x 2 ml solvent
- 5 x 5 doses of lyophilisate + 5 x 10 ml solvent
- 5 x 10 doses of lyophilisate + 5 x 20 ml solvent

- Cardboard box with 20 doses of lyophilisate + cardboard box with 40 ml solvent
- Cardboard box with 50 doses of lyophilisate + cardboard box with 100 ml solvent

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 (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

France
Tél: + 33 (0)241228383

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Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
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Tel: + 39 02 516861

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Slovenija
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Tel: + 420 233 010 242

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