SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis INtranasal RSP Live nasal spray, lyophilisate and solvent for suspension for cattle
Bovilis IntraNasal RSP Live nasal spray, lyophilisate and solvent for suspension for cattle (AT, DE)
Bovilis RSP Live Vet nasal spray, lyophilisate and solvent for suspension for cattle (DK, NO)
Bovilis RSP live vet nasal spray, lyophilisate and solvent for suspension for cattle (FI, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:
Live bovine respiratory syncytial virus (BRSV), strain Jencine-2013: 5.0 – 7.0 $\log_{10}$ $TCID_{50}$*
Live bovine parainfluenza virus type 3 (PI3), strain INT2-2013: 4.8 – 7.3 $\log_{10}$ $TCID_{50}$*

*50% tissue culture infective dose

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Basal B8 medium
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium hydrogen phosphate dihydrate
Solvent:
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Sucrose
Water for injections

Lyophilisate: off-white or cream-coloured cake.
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 calves from the day of birth onwards to reduce clinical signs of respiratory disease and viral shedding from infection with BRSV and PI3.

Onset of immunity:	BRSV:	6 days (for calves vaccinated from the day of birth onwards); 5 days (for calves vaccinated from the age of 1 week onwards);
	PI3:	1 week.
Duration of immunity:		12 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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

The efficacy against BRSV may be reduced by presence of maternally derived antibodies.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated calves may excrete the vaccine strains up to 12 days following vaccination.
It is recommended to vaccinate all calves of the herd.

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[1]. Elevated temperature[2].
Common (1 to 10 animals / 100 animals treated):	Cough[3], increased respiratory rate[4]. Ocular discharge[5].

[1] Mild and transient. Occurs during two days following vaccination.
[2] Minor and transient (very rarely up to 41.1 °C); normally resolves within four days.
[3] Mild and transient. Normally resolves in three days.
[4] Transient. Normally resolves within four days.
[5] Mild and transient. Normally resolves in two 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 its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.
{< > to be adjusted nationally}

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 Nasalgen-C. 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.

Calves can be vaccinated from the day of birth onwards.
Reconstitute lyophilisate with solvent as described below. Ensure that the lyophilisate is completely reconstituted before use. The reconstituted vaccine is an orange/brown to off-pink or pink coloured suspension.
Administer a single dose of 2 ml reconstituted vaccine per animal in one nostril.

Instructions for reconstitution:
1 and 5 dose presentations
For proper reconstitution of the lyophilisate, transfer the solvent to the vial with the lyophilisate (2 ml for the 1 dose, 10 ml for the 5 dose; also see the table below) using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

10 and 20 dose presentations
For proper reconstitution of the lyophilisate, transfer 10 ml of the solvent to the vial with the lyophilisate using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. Completely draw up the vaccine suspension and transfer it back to the solvent vial in order to get the correct dose/volume ratio for the respective presentation (20 ml for the 10 dose, 40 ml for the 20 dose; also see the table below). The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

When vaccinating animals, it is recommended to change syringes or tips of a multi-dose syringe 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

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

At a 10-fold maximum dose, no other signs than those described under section 3.6 have been observed. In individual calves exposed to very high maximum dosages (150-fold maximum dose) signs of moderate to severe respiratory disease have been observed.

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.
{to be completed nationally}

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AD07.

The vaccine stimulates active immunity against bovine respiratory syncytial virus and bovine parainfluenza type 3 virus.

The vaccine stimulates receptors and cytokines involved 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 lyophilisate as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale (2 ml): 3 years.
Shelf life of the solvent as packaged for sale (10 ml, 20 ml, 40 ml): 5 years.
Shelf life after reconstitution according to directions: 6 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.

5.4 Nature and composition of immediate packaging

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

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

Pack sizes:
Cardboard box with:
- 1 dose of lyophilisate + 2 ml of solvent
- 5 doses of lyophilisate + 10 ml of solvent
- 10 doses of lyophilisate + 20 ml of solvent
- 20 doses of lyophilisate + 40 ml of solvent
- 5 x 1 dose of lyophilisate + 5 x 2 ml of solvent
- 5 x 5 doses of lyophilisate + 5 x 10 ml of solvent

- Cardboard box with 10 doses of lyophilisate + cardboard box with 20 ml solvent
- Cardboard box with 20 doses of lyophilisate + cardboard box with 40 ml of 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>.
{< > to be adjusted nationally}

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

{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. {to be completed nationally}

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

{MM/YYYY} {to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX containing vial(s) of lyophilisate and solvent (1, 5,10 and 20 dose presentations) or one vial of lyophilisate (10 and 20 dose presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis INtranasal RSP Live nasal spray, lyophilisate and solvent for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Live BRSV, strain Jencine-2013: 5.0 – 7.0 $\log_{10}$ $TCID_{50}$
Live PI3, strain INT2-2013: 4.8 – 7.3 $\log_{10}$ $TCID_{50}$

3. PACKAGE SIZE

1 dose of lyophilisate + 2 ml of solvent
5 doses of lyophilisate + 10 ml of solvent
10 doses of lyophilisate + 20 ml of solvent
20 doses of lyophilisate + 40 ml of solvent
5 x 1 dose of lyophilisate + 5 x 2 ml of solvent
5 x 5 doses of lyophilisate + 5 x 10 ml of solvent
10 doses of lyophilisate
20 doses of lyophilisate

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 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. 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

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{number} {to be completed nationally}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (solvent only) containing 1 x 20 ml or 1 x 40 ml solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Unisolve
Solvent for Bovilis INtranasal RSP Live

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

20 ml (10 doses)
40 ml (20 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 6 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

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

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{national number}{to be completed nationally}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL – Lyophilisate (vial of 1 dose, 5 doses, 10 doses and 20 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis INtranasal RSP Live

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
5 doses
10 doses
20 doses

Each dose (2 ml):
BRSV: 5.0 – 7.0 $\log_{10}$ $TCID_{50}$
PI3: 4.8 – 7.3 $\log_{10}$ $TCID_{50}$

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 6 hours.

PARTICULARS TO APPEAR ON IMMEDIATE VIAL LABEL OF THE SOLVENT

GLASS VIAL LABEL – Solvent (vial of 2 ml, 10 ml, 20 ml and 40 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Unisolve
Solvent for Bovilis INtranasal RSP Live

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)

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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 INtranasal RSP Live nasal spray, lyophilisate and solvent for suspension for cattle

2. Composition

Each dose (2 ml) contains:
Live bovine respiratory syncytial virus (BRSV), strain Jencine-2013: 5.0 – 7.0 $\log_{10}$ $TCID_{50}$*
Live bovine parainfluenza virus type 3 (PI3), strain INT2-2013: 4.8 – 7.3 $\log_{10}$ $TCID_{50}$*

*50% tissue culture infective dose

Lyophilisate: off-white or cream-coloured cake.
Solvent: clear colourless solution.

3. Target species

Cattle.

4. Indications for use

For active immunisation of calves from the day of birth onwards to reduce clinical signs of respiratory disease and viral shedding from infection with BRSV and PI3.

Onset of immunity:	BRSV:	6 days (for calves vaccinated from the day of birth onwards); 5 days (for calves vaccinated from the age of 1 week onwards);
	PI3:	1 week.
Duration of immunity:		12 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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

The efficacy against BRSV may be reduced by presence of maternally derived antibodies.

Special precautions for safe use in the target species:
Vaccinated calves may excrete the vaccine strains up to 12 days following vaccination.
It is recommended to vaccinate all calves of the herd.

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 on the same day but not mixed with Bovilis Nasalgen-C. 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.

Overdose:
At a 10-fold maximum dose, no other signs than those described under section "Adverse events" have been observed. In individual calves exposed to very high maximum dosages (150-fold maximum dose) signs of moderate to severe respiratory disease have been observed.

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

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Nasal discharge[1]. Elevated temperature[2].
Common (1 to 10 animals / 100 animals treated):	Cough[3], increased respiratory rate[4]. Ocular discharge[5].

[1] Mild and transient. Occurs during two days following vaccination.
[2] Minor and transient (very rarely up to 41.1 °C); normally resolves within four days.
[3] Mild and transient. Normally resolves in three days.
[4] Transient. Normally resolves within four days.
[5] Mild and transient. Normally resolves in two 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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system.
{< > to be adjusted nationally}

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

Nasal use.

Calves can be vaccinated from the day of birth onwards.
Reconstitute lyophilisate with solvent as described below. Ensure that the lyophilisate is completely reconstituted before use.
Administer a single dose of 2 ml reconstituted vaccine per animal in one nostril.

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

9. Advice on correct administration

Instructions for reconstitution:
1 and 5 dose presentations
For proper reconstitution of the lyophilisate, transfer the solvent to the vial with the lyophilisate (2 ml for the 1 dose, 10 ml for the 5 dose; also see the table above) using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

10 and 20 dose presentation
For proper reconstitution of the lyophilisate, transfer 10 ml of the solvent to the vial with the lyophilisate using a needle and syringe. The vacuum in the vaccine vial will allow quick emptying of the syringe. Then resuspend by shaking. Completely draw up the vaccine suspension and transfer it back to the solvent vial in order to get the correct dose/volume ratio for the respective presentation (20 ml for the 10 dose, 40 ml for the 20 dose; also see the table above). The vaccine suspension can be drawn up in a syringe with a clean tip. The vaccine in the syringe is now ready for administration, directly from the tip of the syringe. A spraying device is not required.

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

Visual appearance after reconstitution: orange/brown to off-pink or pink coloured 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.

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.

Shelf life after reconstitution according to directions: 6 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
{< > to be adjusted nationally}

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

{to be completed nationally}

Pack sizes:
Cardboard box with:
- 1 dose of lyophilisate + 2 ml of solvent
- 5 doses of lyophilisate + 10 ml of solvent
- 10 doses of lyophilisate + 20 ml of solvent
- 20 doses of lyophilisate + 40 ml of solvent
- 5 x 1 dose of lyophilisate + 5 x 2 ml of solvent
- 5 x 5 doses of lyophilisate + 5 x 10 ml of solvent

- Cardboard box with 10 doses of lyophilisate + cardboard box with 20 ml of solvent
- Cardboard box with 20 doses of lyophilisate + cardboard box with 40 ml of solvent

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

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>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

{to be completed nationally}