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 AND OTHER 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5024

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

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 AND OTHER 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5024

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGINGUNITS
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. QUALITATIVE AND 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.

5. ROUTE(S) OF ADMINISTRATION

Nasal use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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 SOLVENT

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. ROUTES 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

PARTICULARS TO APPEAR ON THE 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 the veterinary 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: Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06376/5024

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 10 January 2025