# 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 AND OTHER 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. INDICATION(S)

## 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.
Keep the vial 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 14. MARKETING AUTHORISATION NUMBER

Vm 01708/5066

## 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 To be supplied only on veterinary prescription.

# 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 AND OTHER SUBSTANCES

## 3. PACKAGE SIZE

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

## 4. TARGET SPECIES

Cattle.

## 5. INDICATION(S)

## 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.
Keep the vial 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 14. MARKETING AUTHORISATION NUMBER

Vm 01708/5066

## 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 To be supplied only on veterinary prescription.

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

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.

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

1 dose
5 doses
10 doses
20 doses
50 doses

## 6. ROUTE(S) OF ADMINISTRATION

Nasal use.

## 7. WITHDRAWAL PERIOD

Withdrawal period(s): 0 days.

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# PARTICULARS TO APPEAR ON IMMEDIATE DILUENT/SOLVENT LABEL

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

## 1. NAME OF THE DILUENT/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. ROUTES 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.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

# PARTICULARS TO APPEAR ON THE 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

For animal treatment only.

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:
The safety of the veterinary medicinal product has not been established during pregnancy and 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<br>(>1 animal / 10 animals treated): | Nasal discharge, Increased respiratory rate, Cough<br><br>Elevated temperature[1] |
| Common<br>(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: 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.

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

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

Medicines should not be disposed of via wastewater.
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

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.

Vm 01708/5066

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

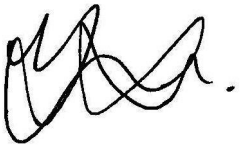
## 16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

## 17. OTHER INFORMATION



Approved: 30 August 2023