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 the package leaflet for respective contact details.

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 – bovine coronavirus

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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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

MSD Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 01708/5066

8. DATE OF FIRST AUTHORISATION

30 August 2023

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

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 17 February 2025