LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX with 10 x 2 ml, 1 x 10 ml, 1 x 40 ml, and 1 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Bovine rotavirus, serotype G6 P5, strain UK-Compton, inac.	≥ 874 U[1]
Bovine coronavirus, strain Mebus, inac.	≥ 340 U[1]
E. coli, serotype O101:K99:F41, strain CN7985, fimbrial adhesins F5 and F41, inac.	≥ 560 U[1]

[1]See package leaflet

3. PACKAGE SIZE

10 ml	5 doses
40 ml	20 doses
100 ml	50 doses
10 x 2 ml	10 x 1 dose

4. TARGET SPECIES

Cattle (pregnant cows and heifers)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. 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

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3043

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABEL - 100 ml (50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Bovine rotavirus, serotype G6 P5, strain UK-Compton, inac.	≥ 874 U
Bovine coronavirus, strain Mebus, inac.	≥ 340 U
E. coli, serotype O101:K99:F41, strain CN7985, fimbrial adhesins F5 and F41, inac.	≥ 560 U

100 ml (50 doses)

3. TARGET SPECIES

Cattle (pregnant cows and heifers)

4. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL – 2 ml (1 dose), 10 ml (5 doses) and 40 ml (20 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bovine rotavirus inac., Bovine coronavirus inac., *E. coli* inac.

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bovilis Rotavec Corona emulsion for injection for cattle

2. Composition

Each dose (2 ml) contains:

Active substances:

Bovine rotavirus, serotype G6 P5, strain UK-Compton, inactivated	≥ 874 U[1]
Bovine coronavirus, strain Mebus, inactivated	≥ 340 U[2]
E. coli, serotype O101:K99:F41, strain CN7985, fimbrial adhesins F5 and F41, inactivated	≥ 560 U[3]

[1] Units as determined in the BRV potency ELISA
[2] Units as determined in the BCV potency ELISA
[3] Units as determined in the *E. coli* F5 (K99) potency ELISA

Adjuvants:

Light mineral oil / emulsifier	1.40 ml
Aluminium hydroxide	2.45 - 3.32 mg

Excipients:

Thiomersal	0.032 - 0.069 mg

Off-white emulsion.

3. Target species

Cattle (pregnant cows and heifers).

4. Indications for use

For the active immunisation of pregnant cows and heifers to raise antibodies against *E. coli* adhesin F5 (K99) and F41 antigen, rotavirus and coronavirus. While calves are fed colostrum from vaccinated cows during the first two to four weeks of life, these antibodies have been demonstrated to:
- reduce the severity of diarrhoea caused by *E. coli* F5 (K99) and F41
- reduce the incidence of scours caused by rotavirus
- reduce the shedding of virus by calves infected with rotavirus or coronavirus.

Onset of Immunity: Passive protection against all active substances will commence from the start of colostrum feeding

Duration of Immunity: In calves artificially fed with pooled colostrum, protection will continue until colostrum feeding ceases. In naturally suckled calves, protection against rotavirus will persist for at least 7 days and against coronavirus for at least 14 days.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Administration in the ischiorectal fossa resulted in local painful chronic granulomatous reactions up to 12 cm in diameter and in abscess formation (up to 1 cm in diameter at post mortem 19 weeks after the first vaccination).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:
Can be used during pregnancy.

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 Cryptium. The vaccines should be given at different sites.
The product literature of Bovilis Cryptium should be consulted before administration. After non-mixed associated use injection site swellings raised up to 1 cm and a diameter of on average 7.6 cm (maximum of 30 cm) can be observed. Swellings usually resorb within 14 to 21 days but may persist for 18 weeks.

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 reactions other than those described in "Adverse events" section occurred following the administration of a two-fold overdose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle (pregnant cows and heifers):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], injection site pain[2], injection site warmth[2], injection site granuloma[3] Muscle inflammation[4] Injection site abscess[5]
Common 1 to 10 animals / 100 animals treated:	Elevated temperature[6]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[7]

[1] Intramuscular administration: Soft swelling raised up to 1 cm and a diameter of on average 6.5 cm (maximum of 25 cm). Swellings usually resorb within 14 to 21 days but may persist for 125 days.
Subcutaneous administration in the neck: Swelling raised up to 1 cm and ranged from 2x2 to 15x15 cm (LxW). Swellings usually resorb over time but may persist for 125 days.
[2] Injection site pain and injection site warmth occur reportedly commonly, when administered intramuscularly.
[3] After subcutaneous administration in the ischiorectal fossa.
[4] Subcutaneous administration in the ischiorectal fossa resulted in granulomatous haemorrhagic inflammatory reaction in dermal and subdermal tissues with inflammation extending into the underlying muscular tissue.
[5] Less than 1 cm in diameter after subcutaneous administration in the ischiorectal fossa.
[6] Intramuscular administration: Average increase of 0.4 °C, with a maximum of more than 2.0 °C, returning to normal the day after vaccination.
Subcutaneous administration in the ischiorectal fossa: Average increase of 0.4 °C, with a maximum of more than 2.0 °C, returning to normal in one to two days after vaccination.
[7] In such cases, appropriate treatment such as adrenaline should be administered without delay.

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

Intramuscular or subcutaneous use.
Preferably administer the vaccine in the side of the neck.

Administration:
Administer a single dose of 2 ml per animal.
The recommended site of injection is the side of the neck. A single injection should be given during each pregnancy between 12 and 3 weeks before calving is expected.

Colostrum feeding: Protection of calves depends on the physical presence of colostrum antibodies (from vaccinated cows) within the gut for the duration of the first 2 - 3 weeks of life until calves develop their own immunity. Thus, it is essential to ensure adequate colostrum feeding for the whole of this period to maximise the efficacy of vaccination. All calves must receive adequate colostrum from their dams within 6 hours of birth. Suckled calves will continue to receive adequate colostrum naturally by feeding from vaccinated cows.
In the dairy herd colostrum/milk from the first 6 - 8 milkings of vaccinated cows should be pooled. The colostrum may be stored below 20 °C, but should be used as soon as possible as immunoglobulin levels may fall by up to 50% after storage for 28 days. Where possible, storage at 4 °C is recommended. The calves should be fed on this pool at the rate of 2½ to 3½ litres per day (according to body size) for the first two weeks of life.

Optimal results will be obtained if a whole herd cow vaccination policy is adopted. This will ensure that in calves the level of infection and consequent virus excretion is kept to a minimum and consequently the overall level of disease challenge on the farm is minimised.

9. Advice on correct administration

Shake well before use.
Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

Strict precautions should be taken against contamination of the vaccine. The use of a multi-dose syringe is recommended to avoid excessive broaching of the stopper. Once a vial is broached for the first time it may be used once more during the next 28 days and then discarded immediately after that use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.
The content of the vial should not be used beyond 28 days after first broaching.
After broaching and first use, store upright and refrigerated (2 °C – 8 °C) until the next vaccination event.

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

Vm 01708/3043

Pack sizes:
Cardboard box with:
- 10 glass vials of 2 ml (10 x 1 dose).
- 1 glass or plastic vial of 10 ml (5 doses).
- 1 glass or plastic vial of 40 ml (20 doses).
- 1 glass or plastic vial of 100 ml (50 doses).

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 <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Marketing Authorisation Holder
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

<Manufacturer responsible for batch release[1]:> {to be adjusted nationally if included in the above}
Burgwedel Biotech GmbH
Im Langen Felde 5
D-30938 Burgwedel
Germany

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<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

Calf diarrhoea is a complex disease of which rotavirus, coronavirus and *E. coli*, are three of the most important causal agents in calves in the first few weeks of life. The vaccine will aid in protecting against disease caused by rotavirus, coronavirus and *E. coli* where these are the sole aetiological agents. The presence of each agent can be

confirmed by laboratory sampling of fresh faeces samples (not swabs) taken directly from calves before any treatment. As the level of passive protection induced by the vaccine is not absolute, coronavirus and rotavirus infections may occur in calves from vaccinated dams- but will be contained whilst the calf is mounting its own active immune response against the viruses.
F5 (K99) and F41 antigens enables *E. coli* to adhere to the calf's intestine where the bacteria multiply rapidly and produce toxins leading to scours, typically in the first few days of life. Specific antibodies can inhibit *E. coli* sticking to the gut wall and thereby their ability to cause disease. The *E. coli* antigen in the vaccine promotes the production of antibodies in colostrum and milk.

{to be completed nationally}

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

Gavin Hall
Approved: 28 October 2024