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 for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

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

[1]See package leaflet

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle (pregnant cows and heifers)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Shake well before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ
UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4556

17. MANUFACTURER'S 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 for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

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

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml (50 doses)

5. TARGET SPECIES

Cattle (pregnant cows and heifers)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Shake well before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ
UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4556

17. MANUFACTURER'S 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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bovine rotavirus, Bovine coronavirus, *E. coli*

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

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

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bovilis Rotavec Corona emulsion for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Burgwedel Biotech GmbH
Im Langen Felde 5
D-30938 Burgwedel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona emulsion for injection for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 2 ml contains:

Active substances

Bovine rotavirus inactivated, strain UK-Compton, serotype G6 P5	≥ 874 U[1]
Bovine coronavirus inactivated, strain Mebus	≥ 340 U[2]
E. coli strain CN7985, serotype O101:K99:F41	≥ 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
Formaldehyde	≤ 0.34 mg

Off-white emulsion.

4. INDICATION(S)

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. ADVERSE REACTIONS

A soft swelling raised up to 1 cm was observed very commonly at the site of injection during safety and clinical studies. These swellings usually resorb within 14 to 21 days.
Hypersensitivity reactions were observed in spontaneous pharmacovigilance reports in very rare cases. In such cases, appropriate treatment such as adrenaline should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (pregnant cows and heifers)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.

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 PERIOD(S)

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.

Shelf life after first opening the container: 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 – 8°C) until the next vaccination event.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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 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 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:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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 (symptoms, emergency procedures, antidotes):
On administration of an intramuscular injection of not more than double the recommended dose, a reaction no more severe than after administration of a single dose may occur.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

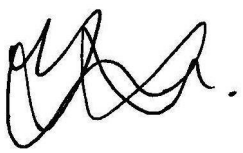
September 2022

15. OTHER INFORMATION

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.

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 Bovilis Rotavec Corona promotes the production of antibodies in colostrum and milk.



Approved: 24 November 2022