SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Cryptium emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance:
Cryptosporidium parvum Gp40[1]: At least 1.0 U[2]

[1] Gp40: Glycoprotein 40
[2] ELISA unit as measured in potency test

Adjuvants:
Montanide ISA70VG: 1140 – 1260 mg
Aluminium hydroxide: 2.45 - 3.32 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
HEPES	
Sodium chloride	
Thiomersal	0.032 – 0.069 mg
Water for injections	

Off-white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (pregnant heifers and cows).

3.2 Indications for use for each target species

For active immunisation of pregnant heifers and cows to raise antibodies in their colostrum against Gp40 of *Cryptosporidium parvum*, intended for passive immunisation of calves to reduce clinical signs (i.e., diarrhoea) caused by *C. parvum*.

Newborn calves:
Onset of immunity: Passive immunity commences from the start of colostrum feeding.
Duration of immunity: In calves that receive colostrum and transition milk as indicated and which were challenged at birth, passive immunity has been demonstrated until 2 weeks of age.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Feeding of calves
The protection of calves depends on adequate ingestion of colostrum and transition milk from vaccinated cows. It is recommended that all calves are fed colostrum and subsequent transition milk during the first 5 days of life. At least 3 litres of colostrum should be fed within the first 6 hours after birth.

To achieve optimum results a whole herd vaccination policy should be adopted.
Farm management should aim at reduction of exposure to *C. parvum*.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Administration in the ischiorectal fossa has resulted in local painful chronic granulomatous reactions up to 15 cm in diameter and in abscess formation (multiple small abscesses up to 1 cm in diameter at postmortem 15 weeks after the first vaccination and 11 weeks after second vaccination) in one out of two necropsied cows (the study included 9 cows).
Administration in the dewlap can give rise to extensive chronic inflammatory reactions up to 30 cm in diameter which can lead to painful local reactions with possible persistent impact on cow welfare.

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 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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Cattle (pregnant heifers and cows):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], injection site pain, injection site warmth, injection site granuloma. Elevated temperature[2].
Uncommon (1 to 10 animals / 1,000 animals treated):	Muscle inflammation[3]. Injection site abscess[4].

[1] Mean size up to 14 cm, maximum size up to 40 cm, swellings reduce in size over time, but may persist as chronic granulomatous inflammation extending from the injection site for at least 125 days.
[2] Mean increase up to 1 °C with a maximum of 1.8 °C, returning to normal on ultimately the 2nd day after vaccination.
[3] Granulomatous haemorrhagic inflammatory reaction in dermal and subdermal tissues with inflammation extending into the underlying muscular tissue.
[4] An abscess up to 1 cm in diameter detected in the neck after the 3rd vaccination.

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:
This veterinary medicinal product is intended for use in the third trimester of pregnancy.

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 Rotavec Corona. The vaccines should be given at different sites.
The product literature of Bovilis Rotavec Corona should be consulted before administration. Different routes of administration should be respected.
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

Subcutaneous use.
Administer the vaccine in the side of the neck.

Allow the vaccine to reach room temperature before use.
Shake well before and occasionally during use to ensure homogeneity of the vaccine prior to administration.
Common aseptic procedures should be used during vaccination.
Only sterile syringes and needles should be used.
Use of a multidose applicator is recommended when vaccinating multiple animals.

One dose: 2 ml.

Primary vaccination consists of 2 doses, 4 to 5 weeks apart, in the third trimester of pregnancy. To be completed at least 3 weeks before calving. These doses are preferably administered at different sides of the animal.

Revaccination consists of 1 dose in the third trimester of each next pregnancy. To be completed at least 3 weeks before calving.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of an overdose, no adverse reactions other than those mentioned in section 3.6 occur.

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: QI02AO02 – *Cryptosporidium.*

The vaccine contains purified *Cryptosporidium parvum* glycoprotein 40 adjuvanted with mineral oil and aluminium hydroxide.
The vaccine is intended to stimulate active immunity of the vaccinated dam in order to provide passive immunity against *Cryptosporidium parvum* to the progeny.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
After broaching and first use, store upright and refrigerated (2 °C – 8 °C) until the next use.

5.4 Nature and composition of immediate packaging

Type I glass vial containing 2 ml or 10 ml, closed with a rubber stopper and an aluminium cap.
PET (polyethylene terephthalate) vial containing 10 ml, 40 ml, or 100 ml, closed with a rubber stopper and an aluminium cap.

Pack sizes:
Cardboard box with 10 x 2 ml (10 x 1 dose).
Cardboard box with 1 x 10 ml (5 doses).
Cardboard box with 1 x 40 ml (20 doses).
Cardboard box with 1 x 100 ml (50 doses).

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
Walton Manor
Walton
Milton Keynes
MK7 7AJ

7. MARKETING AUTHORISATION NUMBER

Vm 01708/5089

8. DATE OF FIRST AUTHORISATION

06 August 2024

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

August 2024

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: 06 August 2024