SUMMARY OF PRODUT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRIVACTON 6

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 5-ml of vaccine contains:

- *E. coli* K99 antigen, at least ……..……..1.15 SA.U
- *E. coli* Y antigen, at least ……..……...0.9 SA.U
- *E. coli* 31A antigen, at least.…….1.6 SA.U
- *E. coli* F41 antigen, at least ……0.7 SA.U
- Inactivated bovine rotavirus, at least …….3.0 SN.U
- Inactivated bovine coronavirus, at least ……1.9 SN.U
- Aluminium hydroxide (expressed in Al^{+++}) ……3.5 mg
- Saponin …….1.5 mg
- Thiomersal* ……...0.5 mg
- Excipient q.s. ……..……..5 ml

1 SA.U: q.s. to obtain an agglutinating antibody titre of 1 $\log_{10}$ in mice after an administration of vaccine.
1 SN.U: q.s. to obtain a neutralising antibody titre of 1 $\log_{10}$ in guinea-pigs after two administrations of vaccine.
* Multidose containers only

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pregnant females)

4.2 Indications for use, specifying the target species

For administration to pregnant cows and heifers to stimulate serological and colostral antibodies against rotavirus and coronavirus antigens and against K99, Y, 31A and F41 antigens of *Escherischia coli* in susceptible animals, which may be passed to the calf to reduce neonatal diarrhoea infection caused by agents containing these antigens.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

None.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to the animals

None.

4.6 Adverse reactions (frequency and seriousness)

. Local reaction at the site of injection (≤10 cm), may appear after vaccination. This usually disappears within 14 days.
. A slight increase in mean rectal temperature (≤0.5°C) may be observed on the day following the injection.
. Any injection of bacterial cells, even inactivated, may occasionally cause hypersensitivity reactions. In such case, a symptomatic treatment should be provided.

4.7 Use during pregnancy, lactation or lay

For vaccination of pregnant cattle.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Shake well before use.
Subcutaneous route.

Inject one 5-ml dose according to the following schedule:

Pregnant cows

- Primary vaccination
  . First injection: 1 to 2 months before calving.
  . Second injection: 2 to 4 weeks after first injection, at least 2 weeks prior to calving.

- Boosters
  No data has been provided to support the use of a single dose booster regime. However, experience in the field suggests that a single dose of the vaccine administered two weeks before calving may provide enhanced antibody levels in the colostrum against the component antigens.
  Ensure that each calf rapidly ingests a sufficient quantity of colostrum.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of a double dose of vaccine, a local reaction at the site of injection may appear as a slight oedema evolving to a firm swelling, usually disappearing within 14 days of vaccination.
A slight transient temperature rise (mean 0.7°C) may be observed for two days following the injection.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Inactivated adjuvanted vaccine which stimulates the production of antibodies to rotavirus, coronavirus and *E. coli.*

ATC Vet Code: QI02AL01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Saponin
Thiomersal (multidose containers only)

6.2 Major incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Open bottle should be used immediately.

6.4 Special precautions for storage

Store between +2°C and +8°C, protected from light.

6.5 Nature and composition of immediate packaging

Nature of basic packaging elements :
Type I glass
Butyl elastomer closure
Aluminium cap

Packaging :
10-dose (glass) bottle, box of 1 bottle.
20-dose (glass) bottle, box of 1 bottle.
1-dose (glass) bottle, box of 10 bottles.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national guidelines.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4106

9. DATE OF FIRST AUTHORISATION

31 May 2001

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 29 November 2018