

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TRIVACTON 6

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of vaccine contains:

Active substance(s):

| | | |
|-----------------------------------|-------|--------|
| Inactivated E. coli (antigen K99) | ≥ 0.6 | SA.U* |
| Inactivated E. coli (antigen Y) | ≥ 0.9 | SA.U* |
| Inactivated E. coli (antigen 31A) | ≥ 1.6 | SA.U* |
| Inactivated E. coli (antigen F41) | ≥ 0.7 | SA.U* |
| Inactivated bovine rotavirus | ≥ 3.0 | SN.U** |
| Inactivated bovine coronavirus | ≥ 1.9 | SN.U** |

Adjuvants: 3.5 mg

Aluminium hydroxide
(expressed in Al⁺⁺⁺)

Saponin 1.5 mg

Excipients: 0.5 mg

Thiomersal 2.5 mg

Excipient q.s. 5.0 ml

* 1SA.U = q.s. to obtain to obtain a seroagglutinating antibody titre of 1 log₁₀ in mice after one administration of vaccine.

** 1SN.U = q.s. to obtain a seroneutralising antibody titre of 1 log₁₀ in guinea-pigs after two administrations of vaccine.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (pregnant cows and heifers).

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 *Escherichia coli* in susceptible animals, which may be passed to the calf via the colostrum to reduce neonatal diarrhoea infection caused by agents containing these antigens.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Optimal results require a whole herd vaccination policy in conjunction with good hygiene practices.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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

In the case of accidental self-injection seek medical advice immediately, and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Local reactions at the site of injection (≤ 10 cm) may appear after vaccination. These usually disappear within 14 days. A slight increase in mean rectal temperature ($\leq 0.5^{\circ}\text{C}$) may be observed for one or two days following the injection. In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

No information is available on the compatibility 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.

Apply usual aseptic procedures.

Inject one 5 ml dose by subcutaneous injection according to the following schedule:

Pregnant cows or heifers

Dose: 5-ml

Administration: subcutaneous injection

Basic vaccination scheme:

First dose: 2 – 6 weeks before calving.

Second dose: at least two weeks after the first dose, a minimum of 14 days before calving (dairy cows) and up to the day of calving (suckler cows).

Re-vaccination scheme:

One dose two weeks before each calving (dairy cows), or during the two week period before calving (suckler cows).

The protection of calves is obtained by ingestion of colostrum: Make sure that each animal rapidly ingests a sufficient quantity of colostrum. Calves must be fed colostrum as follows:

Day 1: early pure colostrum from vaccinated cow sufficient to provide 10 % of the calf weight during the first 24 hours.

During the next three weeks:

Calves born to suckler cows: Allow calves to suckle naturally.

Calves born to dairy cows: Store colostrum by deep freezing. Add colostrum (10 % by volume of the total feed) to the milk substitute.

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 period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI02AL01

Inactivated adjuvanted vaccine for cows, which stimulates the production of antibodies to rotavirus, coronavirus and *E. coli* which may be passed to the calf through colostrum intake.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Salts Water

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life as packaged for sale: 18 months.

Shelf- life after first opening: Use immediately after opening

6.4 Special precautions for storage

Store refrigerated 2°C - 8°C. Protect from light.

6.5 Nature and composition of immediate packaging

Nature of basic packaging elements:

Type I glass
Butyl elastomer closure
Aluminium cap

Packaging:

1-dose (5 ml) bottle, box of 1 bottle.
10-dose (50 ml) bottle, box of 1 bottle.
20-dose (100 ml) bottle, box of 1 bottle.
1-dose (5 ml) bottle, box of 100 bottles.
1-dose (5 ml) bottle, box of 50 bottles.
1-dose (5 ml) bottle, box of 10 bottles.
Not all presentations may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/076/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 August 2003

Date of last renewal: 05 August 2008

10 DATE OF REVISION OF THE TEXT

July 2018