PARTICULARS TO APPEAR ON THE OUTER PACKAGE (10x5 ml, 50 ml and 100 ml carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trivacton 6

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated vaccine containing inactivated bovine rotavirus, inactivated bovine coronavirus and *Escherichia coli* K99, Y, 31A, and F41 antigens with a saponin/aluminium hydroxide adjuvant.

Each dose contains ≥3.0 SN.U inactivated bovine rotavirus, ≥1.9 SN.U inactivated bovine coronavirus and ≥1.15 SA.U K99, ≥0.9 SA.U Y, ≥1.6 SA.U 31A and ≥0.7 SA.U F41 *Escherichia coli* antigens with a saponin (1.5mg)/aluminium hydroxide (3.5mg) adjuvant. Preservative: Thiomersal (0.5 mg).

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 doses
50 ml
1 bottle containing 10 x 5 ml doses.

20 doses
100 ml
1 bottle containing 20 x 5 ml doses.

1 dose
5 ml
10 bottles containing 1 x 5 ml doses

5. TARGET SPECIES

Cows (pregnant cattle).

6. INDICATION(S)

Read enclosed leaflet carefully.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous vaccination.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read enclosed leaflet carefully.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Store between +2°C and +8°C.
Protect from light. Do not freeze.
Open bottles should be used immediately.

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

Read enclosed leaflet carefully.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4106

17. MANUFACTURER'S BATCH NUMBER

Batch:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (50 and 100 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trivacton 6

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An inactivated vaccine containing inactivated bovine rotavirus (≥3.0 SN.U), inactivated bovine coronavirus (≥1.9 SN.U) and *Escherichia coli* K99 (≥1.15 SA.U), Y (≥0.9 SA.U), 31A (≥1.6 SA.U), and F41 antigens (≥0.7 SA.U) with a saponin (1.5mg)/aluminium hydroxide (3.5mg) adjuvant.

Thiomersal: 0.5 mg/ dose (preservative).

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

10 doses - 50 ml
20 doses - 100 ml

5. TARGET SPECIES

Pregnant cattle.

6. INDICATION(S)

Read directions leaflet carefully.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous vaccination.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read directions leaflet carefully.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Store between +2°C and +8°C.
Protect from light. Do not freeze.
Open bottles should be used immediately.

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

Read enclosed leaflet carefully.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4106

17. MANUFACTURER'S BATCH NUMBER

Batch:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (5 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trivacton 6

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated adjuvanted vaccine: inactivated bovine rotavirus (≥3.0 SN.U), inactivated bovine coronavirus (≥1.9 SN.U) and *Escherichia coli* K99 (≥1.15 SA.U), Y (≥0.9 SA.U), 31A (≥1.6 SA.U), and F41 (≥0.7 SA.U) antigens.

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

1 dose – 5 ml

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous injection.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Exp.:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. ADDITIONAL INFORMATION

Read package leaflet carefully before use.

Keep container in outer carton.

PACKAGE LEAFLET FOR: Trivacton 6

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

Boehringer Ingelheim Animal Health UK Ltd,
Bracknell, RG12 8YS, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trivacton 6

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

A suspension for injection containing inactivated bovine rotavirus, inactivated bovine coronavirus and *Escherichia coli* K99, Y, 31A, and F41 antigens with a saponin/aluminium hydroxide adjuvant.

Each dose contains:
• ≥ 3.0 SN.U inactivated bovine rotavirus,
• ≥ 1.9 SN.U inactivated bovine coronavirus,
• ≥ 1.15 SA.U K99 *Escherichia coli* antigen,
• ≥ 0.9 SA.U Y *Escherichia coli* antigen,
• ≥ 1.6 SA.U 31A *Escherichia coli* antigen,
• ≥ 0.7 SA.U F41 *Escherichia coli* antigen.
• Aluminium hydroxide (expressed as Al^{+++}) 3.5 mg per dose
• Saponin 1.5 mg per dose
• Thiomersal (0.5 mg per dose) is added as a preservative (multi-dose containers only).
• 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 an administration of vaccine.

4. INDICATIONS

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 to reduce neonatal diarrhoea infection caused by agents containing these antigens.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Pregnant cows.

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

Administration and dosage
Administer one, 5 ml dose by subcutaneous injection, according to the following schedule:

Pregnant cows and heifers
Primary vaccination:
First injection: 1 to 2 months before calving.
Second injection: 2 to 4 weeks after the first injection, at least 14 days prior to calving date.
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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.
Open bottles should be used immediately.
Check expiry date on pack before use.

Storage
Store between + 2° C and + 8° C, protected from light.
Do not freeze.

12. SPECIAL WARNINGS

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.

Do not mix with any other vaccine or immunological product.
Vaccinate only healthy animals.
Apply usual procedures for the handling of pregnant animals.
Apply the usual aseptic procedures when vaccinating animals.

For Animal Treatment Only

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

Empty vaccine containers should be disposed in accordance with the legislation in force.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Further information
Farmers must ensure that calves receive adequate supplies of colostrum from vaccinated cows within 6 hours of birth and preferably 10% of their bodyweight in colostrum during the first 24 hours of life. Subsequently they should be given colostrum from vaccinated cows throughout the period of risk (2-3 weeks). The feeding of pooled colostrum to calves is recognised as a potential factor in the spread of Johne's disease and as such is not recommended.

Neonatal calf diarrhoea is a multifactorial and complex disease, of which rotavirus, coronavirus and *E. coli* are major causes. Other agents may cause this disease and attention should be paid to all management factors which may influence risk of disease.

Pack sizes
50 ml (10-dose) bottle, box of 1 bottle.
100 ml (20-dose) bottle, box of 1 bottle.
5 ml (1-dose) bottle, box of 10 bottles.

Not all pack sizes may be marketed.

Legal category

POM-V

To be supplied only on veterinary prescription.

Marketing Authorisation Number Vm 08327/4106

Approved: 29 November 2018