ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX 1 x 5 DOSE AND 10 x 1 DOSE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactovac Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5 ml dose contains:

ACTIVE SUBSTANCES:

Inactivated bovine rotavirus, strain 1005/78 ≥ 1 RPU
Inactivated bovine rotavirus, strain Holland ≥ 1 RPU
Inactivated bovine coronavirus, strain 800 ≥ 1 RPU
Inactivated *E. coli* K99/F41, strain S1091/83 ≥ 1 RPU

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 dose (5ml)
1 x 5 doses (25ml)

5. TARGET SPECIES

Cattle (cows and heifers).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.
Shake well before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Protect from frost.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4075

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIALS – 1 DOSE OR 5 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactovac Suspension for injection
Cattle (cows and heifers)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bovine rotavirus, bovine coronavirus, *E.coli* K99/F41.

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

5ml (1dose)
25ml (5doses)

4. ROUTE(S) OF ADMINISTRATION

SC.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Lactovac Suspension for injection

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for the batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactovac Suspension for injection

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

Each 5 ml dose contains:

ACTIVE SUBSTANCES

Inactivated bovine rotavirus, strain 1005/78	≥ 1 RPU*
Inactivated bovine rotavirus, strain Holland	≥ 1 RPU*
Inactivated bovine coronavirus, strain 800	≥ 1 RPU*
Inactivated *E. coli* K99/F41, strain S1091/83	≥ 1 RPU*

* Relative potency unit; RPU = antibody response in rabbit potency test not significantly lower than that obtained with a reference batch shown efficacious in cattle.

ADJUVANTS

Aluminium hydroxide	60 mg
Quil A (*Quillaja saponaria* saponin extract)	1 mg

EXCIPIENTS

Thiomersal	0.05 mg

Pinkish liquid suspension which might contain loose sediment which is easily resuspended.

4. INDICATION(S)

For the active immunisation of pregnant cows and heifers in order to confer passive protection to their calves (via colostrum) to reduce the severity and duration of neonatal diarrhoea caused by rotavirus, coronavirus and *E. coli* (K99/F41) infections.
Protection is conferred only while the calves are fed colostrum from vaccinated cows.

5. CONTRAINDICATIONS

Do not use in animals which have intercurrent infection or are in poor nutritional status.

6. ADVERSE REACTIONS

Immunisation may very commonly result in temporary swellings at the injection site (ranging from small nodules of approximately 1cm in diameter to swellings of 20 cm in diameter in extreme cases). Typically, these swellings completely disappear or reduce to a negligible size within 2-4 weeks after vaccination, though in individual animals very small reactions remain longer. Additionally, a transient slight rise in body temperature normally decreasing to non-significant level within one day may be commonly be expected.

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. Alternatively, you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cattle (cows and heifers).

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

Immunising dose:
One dose of 5 ml.

Method of administration:

Subcutaneous injection into the side of the neck.
Shake well before use.

Basic immunisation:

All cows in a herd should receive two injections of 5 ml during the later stages of pregnancy, with an interval of 4-5 weeks between doses and allowing 2-3 weeks from the time of the second dose until the predicted date of calving.

Re-vaccination:

During each subsequent pregnancy previously vaccinated cows should receive a single injection of 5 ml 2-6 weeks prior to the predicted calving date.

Passive immunisation of the calves:

In order to attain local passive immunisation within the intestine against neonatal diarrhoea, the newborn calves must receive sufficient quality colostrum and milk from the vaccinated dams during the first 10 to 14 days of life. For calves born to beef cows this can be achieved by allowing the calf to suckle naturally. Calves born to dairy cows often do not receive sufficient colostrum if suckled naturally, so artificial feeding of colostrum (e.g. via oesophageal tube feeders) should be used.

Feeding and storage of colostrum
For optimal protection it has been shown that the daily intake of colostrum is essential to the calf from birth to 2 weeks of age. All calves should be fed colostrum derived from the first milking, ideally within the first 6 hours of life. Calves should then either be left to suckle naturally for a minimum of 2 weeks or a colostrum feeding regime must be established. Any remaining quantities from the first milking and all the colostrum from the second milking of each individual dam should be pooled, aliquoted and stored deep frozen (-20 ^{o} C for maximal one year). Alternatively, these colostrum pools can be stored at about +4^{o}C for about 2 weeks. Following the first suckling of colostrum from the dam by the calves, where the calves are separated from the dam, their feed must be supplemented with 500 ml of pooled colostrum from their own dam each day.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 ºC – 8 ºC). Protect from frost.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label after EXP

Shelf life after first opening the immediate package: 10 hours.

12. SPECIAL WARNING(S)

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

Protection of the herd.
Neonatal diarrhoea in calves is caused by pathogens which are constantly present in the herd. For this reason proper control measures require that all pregnant cows and heifers in a herd must be included in the programme of immunisation. This is the only way in which the pressure of infection can be reduced.

Herd hygiene
Neonatal diarrhoea in calves is often associated with poor hygiene. Thus, general improvements in hygiene are important to support the effect of vaccination.

Immune protection
Diarrhoeal diseases can have many causes. The vaccine induces high levels of antibody in the colostrum and milk against rotavirus and coronavirus as well as against *E. coli*, i.e. against the principal pathogens of neonatal diarrhoea in calves.

Special precautions for use in animals:
Not applicable

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. People with known hypersensitivity to any of the components of the product should administer the veterinary medicinal product with caution.

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):
Accidental overdosage is unlikely to cause any reaction other than those described in section 6 (‘Adverse Reactions’) above.

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

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

Medicines should not be disposed of via wastewater or household waste. 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

March 2021

15. OTHER INFORMATION

Type I glass vial containing 5 ml or 25 ml. The glass vial is closed with a type I rubber stopper, sealed with an aluminium crimp cap.

Cardboard box with 1 glass vial of 5 doses (25 ml).
Cardboard box with 10 glass vials of 1 dose (5 ml).

Not all pack sizes may be marketed.

Immunological properties:
To stimulate active immunity with antibody production against rotavirus, coronavirus and *E. coli* (K99/F41) in pregnant cows and heifers in order to provide passive immunity through the colostrum and milk to the progeny against rotaviruses, coronavirus and *E. coli*, i.e. against the principal pathogens of newborn calf diarrhea, as shown by experimental challenge with virulent strains of K99/F41 enterotoxigenic *E. coli*, enteric bovine coronavirus and bovine rotavirus (G6 and G10) belonging to the predominant serotypes in the field.

Approved: 08/10/21