Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Lactovac Suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (cows and heifers).

4.2 Indications for use, specifying the target species

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 colostrums from vaccinated cows.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

Immunisation may very commonly result in temporary swellings at the injection site (ranging from small nodules of approximately 1 cm 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 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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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 5ml 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 5ml 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 ° C for maximal one year). Alternatively, these colostrum pools can be stored at about +4 °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.

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

Accidental overdosage is unlikely to cause any reaction other than those described in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmaceutical group: Immunologicals for Bovidae. Inactivated viral and inactivated bacterial vaccines.
ATC vet code: QI02AL01.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Quil A (Quillaja saponaria saponin extract)
Thiomersal
Sodium Chloride
Potassium Chloride
Magnesium Chloride hexahydrate
Disodium Phosphate dihydrate
Monobasic Potassium dihydrate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate package: 10 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 ºC – 8 ºC).
Protect from frost.

6.5 Nature and composition of immediate packaging

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.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 May 2005
Date of last renewal: 21 May 2010

10 DATE OF REVISION OF THE TEXT

April 2021