Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

IMOCOLIBOV

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains *E. coli* somatic serotypes 09, 08, 015, 078, 0101, 0117, expressing virulence factors:
Active substances:

Antigen K99 of *E. coli*	≥1.22 SA.U*
Antigen Y of *E. coli*	≥1.80 SA.U*
Antigen 31A of *E. coli*	≥1.27 SA.U*
E coli serotype 078	≥1.14 OD Units **

Adjuvants:	
Saponin	0.3 mg
Aluminium hydroxide (expressed in $A1^{+++}$)	0.7 mg

Formaldehyde, at most	1.5 mg
Excipient, q.s	1 ml

* 1 SA.U: q.s. to obtain an agglutinating antibody titre of 1 log 10 in guinea-pigs after two administrations of vaccine.
** OD – Optical Density
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Pregnant cows or pregnant ewes

4.2 Indications for use, specifying the target species

Pregnant cows or pregnant ewes.
Passive immunisation against neonatal *Escherichia coli* infections by administration of the vaccine to pregnant cows or ewes. Reduction of diarrhoea and mortality caused by enterotoxic *E. coli* strains in both lambs and calves.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
None.

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.

4.6 Adverse reactions (frequency and seriousness)

The vaccine may cause the formation of a transient nodule at the site of injection (at most 2 cm) disappearing three to four weeks after vaccination.

Hypersensitivity reactions may occur. In such cases, symptomatic treatment should be provided.
The vaccination may cause a rise in body temperature (generally less than 1°C, but possibly up to 2-2.5°C) that returns to normal 1 or 2 days after vaccination.

4.7 Use during pregnancy, lactation or lay

This product is recommended for use 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

Apply usual procedures for the handling of animals. Shake well before use. Apply usual aseptic procedures.

Optimal results require a whole herd vaccination policy in conjunction with good hygiene. The protection of calves or lambs is obtained by ingestion of colostrum: make sure that each animal rapidly ingests a sufficient quantity of colostrum. For dairy cows, when the calves are separated from their mothers, it is recommended that 2 litres of colostrum per calf is administered at least 3 times during the first 48 hours of life.

Pregnant cows:
Dose: 5 ml
Administration: Subcutaneous route
Basic vaccination scheme – one injection 2 to 6 weeks before calving (if the period of 6 weeks is exceeded, give a second injection).
Re-vaccination scheme: one injection 2 to 6 weeks before each calving.

Pregnant ewes:
Dose: 1 ml
Administration: Subcutaneous route
Basic vaccination scheme -one injection 2 to 6 weeks before lambing (if the period of 6 weeks is exceeded, give a second injection).
Re-vaccination scheme: one injection 2 to 6 weeks before each lambing.

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

No undesirable effects except those mentioned in section 4.6 were observed after administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI02AC and QI04AC.
Inactivated adjuvanted vaccine against neonatal colibacillosis of calves and lambs.

The vaccine stimulates active immunity in pregnant cows or ewes to provide passive immunity to calves/lambs against *E. coli* infection.
The vaccine induces an immune status against antigens K99, Y and 31A of *Escherichia coli,* demonstrated by challenge and by the presence of corresponding specific antibodies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde Salts

6.2 Major incompatibilities

Do not mix with any other vaccine.

6.3 Shelf-life

Shelf-life: 36 months.
Use immediately after opening the bottle.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Protect from light.

6.5 Nature and composition of immediate packaging

5 ml type I glass bottle, box of 1 bottle
50 ml type I glass bottle, box of 1 bottle
50 ml type I glass bottle, box of 50 bottles
50 ml type II glass bottle, box of 1 bottle
50 ml type II glass bottle, box of 50 bottles
Some pack sizes may not be marketed in Ireland

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/063/001

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