[Version 8.2, 01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fencovis suspension for injection (AT, BE, CZ, DE, EL, ES, FR, IE, IT, LU, NL, PT, UK(NI))
Fencovis RCE vet suspension for injection (FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance<s>:

Inactivated *E. coli* expressing F5 (K99) adhesin, strain O8:K35	RP ≥ 1*
Inactivated bovine rotavirus, serotype G6P1, strain TM-91	RP ≥ 1*
Inactivated bovine coronavirus, strain C-197	RP ≥ 1*

* Relative potency (RP): level of antibodies in sera of vaccinated guinea pigs as determined by ELISA in comparison with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test in the target animals.

Adjuvants:

Aluminium hydroxide	6 mg
Quillaja saponin (Quil A)	≤ 0.4 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde	≤ 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Appearance: orange, pink to deep pink liquid with whitish sediment, which is homogenously dispersed after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pregnant heifers and cows).

4.2 Indications for use, specifying the target species

Active immunisation of pregnant heifers and cows in order to stimulate the development of antibodies against bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin and to increase the level of passive immunity of calves against neonatal diarrhoea caused by bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin.
In calves fed with colostrum and milk from vaccinated cows for the first week of life, laboratory studies conducted with heterologous challenge strains (a G6 BRV strain, a BCV strain and a K99 *E. coli* strain) have demonstrated that these antibodies:

- prevent neonatal diarrhoea caused by bovine rotavirus and *E. coli* expressing F5 (K99) adhesin,
- reduce the incidence and severity of neonatal diarrhoea caused by bovine coronavirus,
- reduce faecal shedding of virus in calves infected with bovine rotavirus and bovine coronavirus.

Onset of immunity:

In calves fed with colostrum from vaccinated heifers or cows, passive immunity commences with colostrum feeding and is dependent on calves receiving sufficient colostrum after birth.

Duration of immunity:
Calves fed with colostrum and milk from vaccinated dams for the first week of life are protected against bovine rotavirus for 7 days and against bovine coronavirus for 14 days.
The duration of immunity against infections caused by E. coli expressing F5 (K99) adhesin was not studied since such disease is usually observed in calves less than 3 days of age and susceptibility to enterotoxigenic *E.coli* is age dependent.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
To achieve optimum results and to reduce infection pressure on the farm, a whole herd cow vaccination policy should be adopted, as well as standard infectious diseases control practices.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of adverse reactions following 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)

An increase in mean body temperature of 1.0°C was very commonly observed in laboratory and field studies; in individual cases, the maximum increase may reach 2.1°C, with body temperatures resolving to normal levels within 2 days without impairing the general health status of the vaccinated animals.
A localised mild swelling (≤ 5 cm in diameter) at the injection site resolving within 2 days was commonly observed in field studies.

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 and lactation:
Can be used during pregnancy.
The effect of vaccination on pre- or post-partum lactation was not studied.

4.8 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.

4.9 Amounts to be administered and administration route

Slowly warm up to room temperature and gently shake the content of the vial before administration.

Administration:
One dose of 2 ml by intramuscular injection.
A single injection should be given during each pregnancy between 12 and 3 weeks before the expected calving.

Colostrum feeding:
Calves are born without protection from antibodies. Immunity against calf diarrhoea is provided by rapid uptake of colostral antibodies from vaccinated dams. The first colostrum intake should take place as soon as possible, ideally within 2 hours and at most 6 hours after birth. In dairy calves, it should represent a volume equivalent to approximately 10% of the body weight, followed by a similar volume within 12 hours. Beef calves should stand and suckle within 2 hours of calving.

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

Not applicable.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Bovidae, inactivated viral and inactivated bacterial vaccines for cattle.
ATCvet code: QI02AL01

Vaccination of pregnant heifers and cows induces specific antibodies that are present at high levels from 3 to 12 weeks after vaccination for passive immunisation of calves via colostrum intake against bovine rotavirus, bovine coronavirus and *E. coli* expressing F5 (K99) adhesin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminiun hydroxide
Quillaja saponin (Quil A)
Formaldehyde
Thiomersal
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injection

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 packaging: 10 hours

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Once open, the vials should not be stored above 25°C.
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vials of 3 or 10 ml with chlorobutyl elastomer closure and aluminium or flip off caps.
Type II glass vials of 50 or 100 ml with chlorobutyl elastomer closure and aluminium or flip off caps.
Translucent plastic (HDPE) vials of 15, 60 or 120 ml with chlorobutyl elastomer closure and aluminium or flip off caps.

Plastic box of 2, 10 or 20 glass vials of 1 dose (2 ml)
Cardboard box of 1 glass or plastic vial of 5 doses (10 ml)
Plastic box of 5 or 10 glass or plastic vials of 5 doses (10 ml)
Cardboard box of 1, 12 or 24 glass or plastic vials of 25 doses (50 ml)
Cardboard box of 1 glass or plastic vial of 50 doses (100 ml)

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

To be completed after the Marketing Authorisation

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed after the Marketing Authorisation

10. DATE OF REVISION OF THE TEXT

To be completed after the Marketing Authorisation

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.