Issued: July 2024
AN: 03902/2022

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rokopig Entero emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Porcine rotavirus, serogroup A, strain OSU 6, inactivated	RP ≥ 1*
Escherichia coli, serotype O149:K88 (F4ac), inactivated	RP ≥ 1*
Escherichia coli, serotype O101:K99 (F5 and F41), inactivated	RP ≥ 1* (F5), RP ≥ 1* (F41)
Escherichia coli, serotype K85:987P (F6), inactivated	RP ≥ 1*
Clostridium perfringens, type C, beta toxoid	RP ≥ 1*, **

F = fimbrial adhesin

* RP = Relative potency (ELISA), in comparison with reference serum obtained from vaccinated mice with vaccine batch, which complied in challenge test on target species.

** minimal listed value complies with potency ≥ 20 IU required by Ph. Eur.

Adjuvant:

Montanide ISA 35 VG 0.52 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Formaldehyde	max. 1 mg
Sodium hydrogenphosphate dodecahydrate	
Potassium dihydrogenphosphate	
Sodium chloride	
Water for injections	

White oleic liquid with easily shakeable sediment.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant gilts and sows)

3.2 Indications for use for each target species

For passive immunisation of newborn piglets by active immunisation of pregnant gilts and sows to reduce:

- Clinical signs (neonatal diarrhoea) and mortality caused by *E. coli* strains expressing the fimbrial adhesins F4ac, F5, F6 and F41
- Clinical signs (neonatal diarrhoea, vomiting and anorexia) caused by porcine rotavirus
- Clinical signs (neonatal diarrhoea, enteritis) and mortality caused by beta toxin (expressed by *Clostridium perfringens*)

Onset of immunity:
Passive immunity commences with suckling of piglets and is dependent on piglets receiving sufficient colostrum and milk from vaccinated dams after birth.
Protection of piglets for the indications above were demonstrated for:
E. coli strains: within 12 hours after birth.
Rotavirus: at 5 days of age.
Clostridium perfringens, type C, beta toxoid: at 2 days of age.

Duration of immunity:
Demonstrated based on challenge studies: 3 weeks of age.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
The first intake of colostrum by each piglet in the litter should take place within first 6-8 hours of birth.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (pregnant gilts and sows):

Very common (>1 animal / 10 animals treated):	Elevated temperature [1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling [2]

[1] Mild increase of body temperature (maximum increase observed in individual animals of 0.7 °C, with a maximum duration of 4 days post-vaccination).

[2] Mild swelling of maximum diameter 10 mm, which persists for a maximum of 3 days post-vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder, or its local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

To be used during pregnancy according to the vaccination schedule described in section 3.9.

3.8 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.

3.9 Administration routes and dosage

Vaccine dose: 2 ml

Route of administration: intramuscular use

Administer into the neck muscles behind the ear (paraauricular region).

Allow the vaccine to warm up to approximately 15-25 °C before use and shake the contents well prior to administration. Use sterile injection needle and syringes and administer the vaccine to an area of aseptically treated, clean and dried skin.

Pregnant gilts and sows

Basic vaccination – 2 administrations of one dose at an interval of 2 weeks:

- first administration 4 weeks before expected farrowing
- second administration 2 weeks before expected farrowing

Revaccination
- during subsequent pregnancies: administration of 1 dose 2 weeks prior expected farrowing

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI09AL09

The vaccine contains inactivated porcine rotavirus, serogroup A, selected serovars of inactivated enterotoxigenic *E. coli* strains, pathogenic for suckling piglets, containing F4ac, F5, F41 and F6 fimbria adhesins and also toxoid β (sensu lato) *Clostridium perfringens*, type C (produces α- and β_1-, β_2-toxin).

Vaccination of pregnant sows and gilts stimulates the generation of neutralising antibodies against the antigenic components listed above. These antibodies are transferred via the colostrum and milk to the piglets to provide passive immunity against colibacilosis, acute necrotic enteral clostridial infection and rotaviral disease while suckling.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is filled in:
- glass vials:
hydrolytic class I: 10 ml vial with 10 ml content (5 doses)
hydrolytic class II: 50 ml vial with 50 ml content (25 doses)
100 ml vial with 100 ml content (50 doses)

- plastic (HDPE) vials: 60 ml vial with 50 ml content (25 doses)
120 ml vial with 100 ml content (50 doses)
250 ml vial with 250 ml content (125 doses)

All types of vials are closed with chlorobutyl rubber injectable stopper and covered by aluminium or flip-off cap and inserted to the cardboard or plastic box.

The product is delivered in the following package sizes:
Cardboard box:
1 × 5 doses (10 ml)
1 × 25 doses (50 ml)
1 × 50 doses (100 ml)
1 × 125 doses (250 ml)
Plastic box:
10 × 5 doses (10 × 10 ml)
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a. s.

7. MARKETING AUTHORISATION NUMBER

Vm 46608/3001

8. DATE OF FIRST AUTHORISATION

05 July 2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database
(https://medicines.health.europa.eu/veterinary).

Gavin Hall

Approved: 05 July 2024