A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
cardboard box / 1 × 10 ml (5 doses), 1 × 50 ml (25 doses), 1 × 100 ml (50 doses), 1 × 250 ml (125 doses)
plastic box / 10 × 10 ml (10 × 5 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rokopig Entero emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Active substances:

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

*,** For details see package leaflet.

3. PACKAGE SIZE

1 × 10 ml (5 doses)
1 × 50 ml (25 doses)
1 × 100 ml (50 doses)
1 × 250 ml (125 doses)
10 × 10 ml (10 × 5 doses)

4. TARGET SPECIES

Target species: Pigs (pregnant gilts and sows).

5. INDICATIONS

N/A

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOVETA, a.s.

14. MARKETING AUTHORISATION NUMBERS

Vm 46608/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

etiquette for glass vials / 100 ml (50 doses)
etiquette for plastic vials / 100 ml (50 doses), 250 ml (125 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rokopig Entero emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Active substances:
Inactivated:

Porcine rotavirus, serogroup A, OSU 6	RP ≥ 1
E. coli O149:K88 (F4ac)	RP ≥ 1
E. coli O101:K99 (F5 and F41)	RP ≥ 1 (F5), RP ≥ 1 (F41)
E. coli K85:987P (F6)	RP ≥ 1
C. perfringens, type C, beta toxoid	RP ≥ 1

For details see package leaflet.

100 ml (50 doses)
250 ml (125 doses)

3. TARGET SPECIES

Target species: Pigs (pregnant gilts and sows)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOVETA, a.s.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

etiquette for glass vial / 10 ml (5 doses), 50 ml (25 doses)
etiquette for plastic vial / 50 ml (25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rokopig Entero

{logo}

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Inactivated:
Porcine rotavirus, serogroup A, OSU 6; *E. coli* O149:K88 (F4ac); *E. coli* O101:K99 (F5 and F41); *E. coli* K85:987P (F6); *C. perfringens*, type C, beta toxoid
RP ≥ 1 for each component - see package leaflet.

10 ml (5 doses)
50 ml (25 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rokopig Entero emulsion for injection

2. 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

White oleic liquid with easily shakeable sediment.

3. Target species

Pigs (pregnant gilts and sows)

4. Indications for use

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 in piglets:
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 in piglets:

Demonstrated based on challenge studies:	3 weeks of age.

5. Contraindications

None.

6. Special warnings

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.

Pregnancy:
To be used during pregnancy according to the vaccination schedule described in section “Dosage for each species, routes and method of administration”.

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.

Major incompatibilities:
Do not mix with any other veterinary medicinal products.

7. 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 product. 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 contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Vaccine dose: 2 ml
Route of administration: intramuscular use.
Administer into the neck muscles behind the ear (paraauricular region).

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 46608/3001

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Bioveta, a.s.
Komenskeho 212/12
Ivanovice na Hané
683 23
Czech Republic

Tel. 00420 517 318 911
email: reklamace@bioveta.cz

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

Local representatives

Animal Health Distributors
Industrial Estate
Tullow
Co. Carlow
UK(NI) only:
sdmhouse@blueyounder.co.uk
tel.: 00 353 86 770 3502

IE only
tfleming@cahg.ie
tel.:00 353 87 2302034
kfeehily@cahg.ie
tel.:00 353 86 199 2736

<17. Other information>

Gavin Hall
Approved: 28 November 2024